

MINIMALLY-INVASIVE SURGICAL INSTRUMENT AND MODIFIED RATCHET

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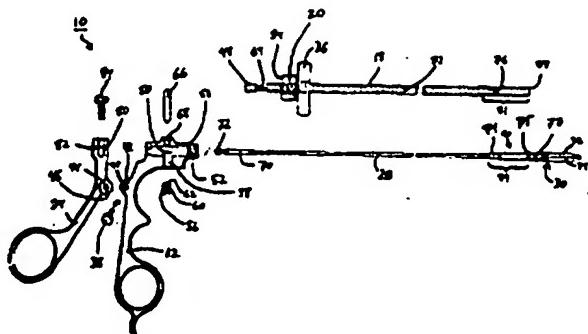
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Abstract of WO9513023

A minimally-invasive surgical instrument is provided including front and rear handles mounted pivotally relative to each other. A shaft is mounted to the front handle and an actuating rod connected to the rear handle passes through the shaft and is moveable longitudinally relative thereto, the actuating rod having a proximal end coupled to the rear handle and a distal end coupled to a jaw assembly. The jaw assembly may be securely fastened at the distal end of the shaft. Cleaning holes may be provided at strategic locations in the instrument for cleaning capability and individual components of the instrument are



interchangeable with other components to provide flexibility in terms of shaft length, jaw assembly function, and the like. The instrument is specifically designed so that any interchange of instrument components may be effected only by releasing securing mechanisms at portions of the instrument that remain outside of a patient during surgery. The instrument may be provided by captured fasteners so that loss and/or contamination of fasteners is avoided. The instrument can include a modified ratchet mechanism including a trigger movable by a surgeon and an impinging member mounted adjacent the actuating rod and secured to the trigger and movable from a position allowing the actuating rod to move longitudinally relative to the shaft, and a position securing the rod against such movement.

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<p>(54) Title: MINIMALLY-INVASIVE SURGICAL INSTRUMENT AND MODIFIED RATCHET</p> <div style="text-align: center;"> </div> <p>(57) Abstract</p> <p>A minimally-invasive surgical instrument is provided including front and rear handles mounted pivotally relative to each other. A shaft is mounted to the front handle and an actuating rod connected to the rear handle passes through the shaft and is moveable longitudinally relative thereto, the actuating rod having a proximal end coupled to the rear handle and a distal end coupled to a jaw assembly. The jaw assembly may be securely fastened at the distal end of the shaft. Cleaning holes may be provided at strategic locations in the instrument for cleaning capability and individual components of the instrument are interchangeable with other components to provide flexibility in terms of shaft length, jaw assembly function, and the like. The instrument is specifically designed so that any interchange of instrument components may be effected only by releasing securing mechanisms at portions of the instrument that remain outside of a patient during surgery. The instrument may be provided by captured fasteners so that loss and/or contamination of fasteners is avoided. The instrument can include a modified ratchet mechanism including a trigger movable by a surgeon and an impinging member mounted adjacent the actuating rod and secured to the trigger and movable from a position allowing the actuating rod to move longitudinally relative to the shaft, and a position securing the rod against such movement.</p>									

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MINIMALLY-INVASIVE SURGICAL INSTRUMENT AND MODIFIED RATCHET

FIELD OF THE INVENTION

The present invention relates generally to minimally-invasive surgical instruments, more particularly to a reusable and limited-use laparoscopic instrument and a modified ratchet mechanism for immobilizing a movable surgical tool of a minimally-invasive surgical instrument.

BACKGROUND OF THE INVENTION

Laparoscopic surgery is a procedure in which one or more small incisions are made in a patient, and one or more instruments are inserted through a cannula positioned in the incision to effect an internal surgical procedure. For example, a camera with a light source may be inserted through a cannula to provide a surgeon with means for viewing his or her work, a manipulating tool such as a clamp, dissector, cauterizer or the like may be inserted through another cannula and another instrument, irrigator, or the like may be inserted through yet another cannula. The technique involves significantly less incising and tissue damage than do traditional surgical procedures, and results in recovery periods shorter than those normally associated with traditional surgical procedures. Laproscopy has been indicated for gynecological, abdominal, urological, orthopedic, thoracic, and other surgical procedures.

A typical laparoscopic instrument includes a shaft, a handle secured to the shaft, and a surgical tool secured to the shaft and spaced from the handle. The surgical tool may be operably linked to the handle by way of an actuating rod associated with the shaft. In this way, the surgical tool may be inserted into a patient during surgery, and may be manipulated by a surgeon (outside of the patient) by way of the handle. For example, a surgeon may move the handle

between a first position and a second position, which in turn moves a surgical clamp between an open and a closed position.

Many laparoscopic instruments are prone to failure. The fact that a limited number of passages, each of limited dimension, are created to allow the surgeon to address the work site means that any portion of any laparoscopic instrument becoming detached from the instrument within the patient may not be easily removed, if the portion is not easily oriented so as to be withdrawn from the patient through one of the passages. Additionally, the field of view of laparoscopic cameras is typically far inferior to a surgeon's field of view during traditional surgical procedures. Therefore, detachment of any portion of any laparoscopic instrument within the patient may not be noticed and the detached portion may remain in the patient after surgery.

Laparoscopic instruments must, of course, be sterile prior to use. Typically, such instruments are sold in sterile packaging and are discarded after one use, or are designed to be reusable with sterilization. The term "reusable", as used with reference to laparoscopic instruments, is generally meant to define use until failure. The use of reusable instruments may create a safety hazard as the point of failure of a particular instrument may not be determinable prior to its occurrence.

The use of disposable instruments is seldom cost effective. A plurality of instruments may be removed from packaging prior to a surgical procedure, many of them may not be needed during the procedure, but all must be discarded. In an effort to make such instruments disposable yet cost effective, durability may be compromised, creating a safety hazard. Another problem associated with disposable instruments is the environmental impact on such disposal. Disposable instruments create a large biomedical hazardous waste trail as well as wasting natural resources. The environmental issue of hazardous waste also has an economic impact on a hospital due to the cost of disposal.

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As an alternative to reusable and disposable instruments, an attempt has been made to developed so-called "limited use" laparoscopic instruments. By definition, such instruments are designed to be used a predetermined number of times, with sterilization between each use, and then discarded. However, heretofore known limited use laparoscopic instruments are actually reusable by definition. Inspection of such an instrument gives no indication as to the number of procedures in which the instrument has been utilized. The instrument is typically used until it is suspected that the instrument's lifetime is near an end, in a manner identical to the evaluation of reusable instruments in this regard. Record keeping of the number of uses of such instruments would be administratively taxing, and would be unreliable. Such record keeping would be more daunting with modern laparoscopic instrumentation in which parts are interchangeable between instruments. Upon observation of any given instrument, it would be difficult to determine the number of uses to which each component of the instrument had been subject.

The issue of interchangeability of components between various instruments raises another safety concern. Often times the distal portion of the instrument designed to address tissue within the patient is detachable from the instrument to allow and interchanged with another distal tip constructed to effect a different manipulation. For example, a laparoscopic clamp may be removed and replaced with scissors or the like. A significant safety hazard arises if the manipulating portion inadvertently becomes detached within the patient.

Interchangeability of components creates yet another problem. Many instruments designed to be disassembled are disassembled by disconnecting fasteners which are then physically removed from the instrument. For example, one portion of an instrument may be removably coupled to another portion of the instrument with use of a removable screw or

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the like. If such a removable fastener is located on a portion of the instrument inserted into a patient during surgery, the removability of the fastener presents a hazard. Even if such a removable fastener is located on a portion of the instrument remaining outside of a patient during surgery, such a fastener may become lost when removed. Additionally, if such a fastener is removed during surgery, it may become separated and move into a non-sterile environment, from which it may not be returned to the instrument. For example, it may fall on the floor.

Sanitary considerations of reusable laparoscopic instruments may present an additional complication. Such instruments typically include intricate moveable mechanisms designed to be manipulated within a patient, and include mechanical components, between which the tolerances are large enough to trap and retain tissue, even if not exposed to tissue directly, but small enough so that removal of the tissue from the instrument is difficult. This may create a significant cross-contamination hazard. Heretofore known instruments are typically cleaned of such contamination by exterior rinse or by passing fluid through flush ports, which add locations for trapping tissue and through which complete cleaning is not often achieved.

In many instances it is desirable to secure a movable surgical tool against movement. For example, if a surgical clamp is closed on a vessel, duct, tissue, or the like, it may be desirable to lock the clamp in the closed position so that the surgeon may release the handle without releasing the vessel, duct, or tissue.

Modern minimally-invasive surgical instruments typically include interchangeable components. For example, components may be interchangeable between instruments, or a single instrument may be provided with a variety of surgical tools, any one of which may be secured to the instrument at a time. While such interchangability is an advantage, a problem arises from the interchangeability of components of

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heretofore known minimally-invasive surgical instruments. Many instruments designed to be disassembled are disassembled by disconnecting fasteners which are then physically removed from the instrument. For example, one portion of an instrument may be removably coupled to another portion of the instrument with use of a removable screw or the like. Such a fastener may become lost when removed. Additionally, if such a fastener is removed during surgery, it may become separated and move into a non-sterile environment, from which it may not be returned to the instrument. For example, it may fall on the floor. This creates, in essence, a safety hazard.

SUMMARY OF THE INVENTION

It is an object of the present invention to provide a minimally-invasive surgical instrument that may be disassembled into a plurality of components, while providing one that presents no safety hazard as a result of the ability to effect disassembly. It is an object that some of the components be interchangeable with those of other similar instruments and some of the components be reusable, while others be limited use components by definition. It is another object of the invention to provide an instrument that is easily cleanable, that is, one in which all portions of the instrument may be conveniently addressed by cleansing fluid or the like. Other objects of the present invention include provision of a surgical instrument that is of relatively simple, yet highly durable mechanical construction, and that allows for relatively inexpensive maintenance of a wide variety of surgical capability within an operating room at any given time.

It is also an object of the invention to provide a minimally-invasive surgical instrument including a movable surgical tool which may be conveniently secured against movement by a surgeon. It is another object of the invention to provide an instrument which may be disassembled into a plurality of components, while providing one that presents no

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safety hazard as a result of the ability to effect disassembly.

The present invention provides a surgical instrument including a portion designed to be inserted into a patient and carrying a mechanism for manipulating tissue within a patient, the manipulating mechanism operably linked to a control mechanism designed to reside outside of a patient and to be actuated by an operator. The instrument may be disassembled into a plurality of individual components, many of which are interchangeable with those of a variety of instruments provided according to a variety of inventive embodiments. Disassembly may be effected only by disconnection of a fastener on the portion of the instrument that remains outside of the patient during surgery, thus loss of an instrument component within a patient is minimized. The interchangeability of instrument components allows for surgical staff to quickly and easily change the length of an instrument shaft designed to be inserted through a cannula during surgery, and to easily change tissue-manipulating mechanisms.

The invention provides a reusable instrument, limited-use instrument, or a combination reusable and limited-use instrument. That is, every component of the instrument may be reusable, every component of the instrument may be of limited use, or reusable and limited use components may, together, define a particular instrument. Limited-use components of the instrument are truly limited-use by definition, that is, they may be subjected to a predetermined number of procedures only, the number of procedures being determinable upon inspection of the component at any given time. This is accomplished by providing removable use indicators. Such indicators may indicate the number of uses of the instrument, the number of uses remaining, the number of sterilization procedures to which the instrument has been subjected, or a combination, and may be removable manually or automatically. Automatically removable indicators may be

chemically or physically responsive to sterilization conditions.

The inventive instrument is durable in that the tissue-manipulating mechanism portion provides significant clamping or cutting torque with a minimum of stress at portions of mechanism components vulnerable to failure. Additionally, certain components for actuating the tissue-manipulating mechanism are integral with adjacent actuating components, adding strength and reliability to the overall actuating mechanism and reducing the likelihood of failure.

Each of the components of the inventive instrument is designed to be easily cleanable. In particular, components of the instrument being moveable relative to adjacent components with relatively close tolerances therebetween, even if such components do not directly contact tissue during surgery, may be provided with one or more cleaning holes if not otherwise easily addressable by a cleaning fluid or the like.

Also provided in accordance with the present invention is a ratchet mechanism for a surgical instrument or the like, easily manipulated by a surgeon without movement of the surgeon's hand away from the normal grasping position of the instrument between a first position in which the actuating mechanism of the instrument may be freely moveable between several positions, and a second position in which the actuating mechanism of the instrument is firmly held in one position.

According to one aspect an impinging member is mounted adjacent the actuator on the proximal end of the instrument, for example on the proximal end of the shaft, on the handle, or on the tool-manipulating mechanism and is movable between a first impinging member position in which the actuator is freely movable between the first and second actuator positions, and a second impinging member position engaging

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the actuator and securing the actuator against movement between the first and second actuator positions.

According to one aspect of the invention the handle serves as the tool-manipulating mechanism and is movable between a first and a second handle position defining the first and second tool-manipulating positions, respectively.

According to another aspect of the invention the impinging member is positioned adjacent any of a continuum of locations on the actuator between a first and a second point when the actuator moves between the first and second actuator positions. According to this aspect the impinging member is movable between its first position, and its second position engaging the actuator at any of the continuum of locations and preventing the actuator from movement.

The present invention also provides a minimally-invasive surgical instrument including a shaft, a surgical tool secured to the shaft, a handle secured to the shaft and spaced from the surgical tool, an actuator associated with the shaft, and an impinging member mounted adjacent the actuator. The surgical tool is movable between a first and a second operating position, and the handle is movable between a first and a second handle position. The actuator is movable between a first and a second actuator position, and is operably linked to both the handle and the surgical tool. In this way the actuator effects movement in the tool between the first and second operating positions when the handle is moved between the first and second handle positions, respectively. The impinging member is movable between a first position in which the actuator is freely movable between its first and second positions, and a second position engaging the actuator and securing it against movement between its first and second positions.

BRIEF DESCRIPTION OF THE DRAWINGS

Fig. 1 is a perspective view of a minimally-invasive surgical instrument according to one embodiment of the

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present invention;

Fig. 2 is an illustration of the instrument illustrated in Fig. 1, disassembled;

Fig. 3 illustrates a mechanism for linking a rear handle with an actuating rod according to one embodiment of the present invention;

Fig. 4a is a top view illustrating a mechanism for linking a rear handle with an actuating rod according to another embodiment of the present invention;

Fig. 4b is a cross-sectional view through lines 4b-4b of Fig. 4a;

Fig. 5 is a side view of a disassembled clevis and jaw assembly according to one embodiment of the present invention;

Fig. 6 is a top view of the disassembled clevis and jaw assembly illustrated in Fig. 5;

Fig. 7 is a top view of an assembled jaw assembly according to one embodiment of the present invention, in closed position;

Fig. 8 is a top view of the jaw assembly illustrated in Fig. 7, in open position;

Fig. 9 illustrates a ratchet mechanism according to one embodiment of the present invention, in unratched position;

Fig. 10 shows the ratchet mechanism illustrated in Fig. 9 in ratcheted position;

Fig. 11 is a perspective view of a handle assembly and impinging member trigger according to the embodiment illustrated in Fig. 1;

Fig. 12 illustrates a trigger according to another embodiment of the present invention;

Fig. 13 is a cross-sectional view through line 13-13 of Fig. 11;

Fig. 14 is a cross-sectional view of a shaft mount, trigger, and impinging members according to another embodiment of the present invention;

Fig. 15 is a cross sectional view of a shaft mount, trigger, impinging member, and cam impinger according to

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another embodiment of the present invention;

Fig. 16 is a cross-sectional view of a shaft mount, trigger, and impinging member according to another embodiment of the present invention; and

Fig. 17 is a cross-sectional view of a shaft mount, trigger, impinging member, and ramp according to yet another embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Referring to Fig. 1, a perspective view of a minimally-invasive surgical instrument, specifically a laparoscopic instrument, according to a preferred embodiment of the present invention is illustrated generally at 10. A distal end 11 of instrument 10 is designed to be inserted into a patient and includes a surgical tool, while a proximal end 13 remains outside of the patient and includes a handle for actuating the surgical tool.

Proximal end 13 includes a front handle 12, including a finger hole 14 and a surface 16 formed to accommodate the fingers of operating personnel. Front handle 12 mounts a shaft 18 by way of threaded coupling between a bee nut 20 on shaft 18, and a threaded portion (not shown) of shaft mount portion 15 of front handle 12. Shaft mount portion 15 of front handle 12 also may include an electrode (not shown) for providing electrical communication with an operating tool, such as in an electrocautery procedure. Shaft 18 is constructed and arranged to pass through a laparoscopic cannula. A rear handle 24, including a thumb hole 25, is attached to front handle 12 such that the two handles may pivot relative to each other at a hinge 26, between first and second positions. Hinge 26 pivots on a thumb screw (not shown). Rear handle 24 is adapted to secure a proximal end of an actuating rod 28, which is supported within shaft 18 and may move longitudinally relative thereto.

Distal end 11 of instrument 10 carries a surgical tool, for example a jaw assembly 30, coupled to a distal end of

actuating rod 28 (described below). Jaw assembly 30 includes a first jaw member 32 and a second jaw member 34, which are caused to move relative to each other from a first, closed position to a second, open position upon relative movement of handles 12 and 24 between a first position and a second position. According to one embodiment, one of jaws 32 or 34 is fixed while the other jaw is moveable relative to the fixed jaw, and according to another embodiment, jaws 32 and 34 both move during opening and closing motion. Jaw assembly 30 and handles 12 and 24 are operably linked via actuating rod 28. A Star wheel 36, secured to shaft 18, may be rotated clockwise or counterclockwise through a plurality of detented, radial positions relative to handles 12 and 24, so as to rotate shaft 18 and jaw assembly 30 independently of handles 12 and 24. The particular design of star wheel 36 is not important to the invention. Any of a variety of easily graspable members, secured to shaft 18, could be employed for rotating shaft 18 through the detented, radial positions.

A trigger 242 is pivotally mounted on shaft mount portion 15 of front handle 12 at an impinging member 240, and these components define, in part, a modified ratchet in accordance with the present invention. Trigger 242 may be moved between a first position allowing actuating rod 28 to freely move axially within shaft 18, and a second position securing rod 28 from movement, and this is described more fully below.

Fig. 2 illustrates instrument 10 (without trigger and impinging member) in a disassembled state showing detail of inter-component assembly. Rear handle 24 may be attached to front handle 12 at hinge 26, defined by a thumb screw 38 which, according to one embodiment, threads through a front hole 40 of a slotted bracket 42 of front handle 12, passes freely through a hole 44 of a pivot member 46 of rear handle 24 and, finally, threads through a rear hole (not shown) of slotted bracket 42. According to a particularly preferred embodiment, thumb screw 38 is a captured screw, and is retained in front hole 40 of slotted bracket 42 upon disassembly.

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A proximal portion 48 of shaft 18 may be inserted into a sleeve 50 within front handle 12, and secured therein by engagement of bee nut 20 having interior threads (not shown) with a threaded portion 52 of front handle 12. Secure attachment is achieved when a face 54 of bee nut 20 firmly engages a lip 56 of front handle 12. A threaded cam ball plunger assembly 56 threads into a ball plunger assembly port 58 of front handle 12 and includes a spring 60 and a cam ball 62 which, when assembly 56 is firmly threaded into port 58, extends into sleeve 50. When proximal portion 48 of shaft 18 is inserted into sleeve 50, one of a plurality of radially disposed detents 64 is caused to align with cam ball 62, and ball 62 engages one of detents 64 to retain shaft 18 and jaw assembly 30 in one of a plurality of radial orientations. Star wheel 36 is secured to shaft 18, or is integral therewith, and may be rotated so as to cause cam ball 62 to engage one of the several detents 64, so as to orient jaw assembly 30 in one of a variety of radial positions relative to the handle assembly.

Electrode 66, mounted in an electrode port 68, contacts proximal portion 48 of shaft 18 so as to provide electrical communication therewith. Electrode 66 may be threadingly inserted into port 68 or, as shown, may be provided therein with a friction fit.

Actuating rod 28 and jaw assembly 30 may be inserted into shaft 18 and secured therein prior to, or subsequent to attachment of shaft 18 to front handle 12. As described below, according to a preferred embodiment actuating rod 28 is coupled to jaw assembly 30 in a way that rod 28 and assembly 30 are not detachable from each other without tools of some sort. Actuating rod 28 includes a proximal guide portion 70 and a connecting ball 72. Guide portion 70 is of a diameter slightly smaller than an interior bore 73 of shaft 18. Other portions of actuating rod 28 may be of any diameter equal to or smaller than the diameter of guide portion 70. When actuating rod 28 is inserted into bore 73

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of shaft 18, threads 74 of clevis 90 engage interior threads 76 of shaft 18. When clevis threads 74 are threaded into interior threads 76, a lip 75 of jaw assembly 30 is caused to securely engage a face 78 of the distal end of shaft 18. Such secure engagement causes shaft 18, jaw assembly 30, and actuating rod 28 to rotate axially as one. Portion 79 of clevis 90 fits within portion 81 of shaft 18. In this way, the durability of the junction between jaw assembly 30 and shaft 18 is maximized; any force perpendicular to the axis of shaft 18 imparted onto jaw assembly 30 is counteracted by the overlap of portion 79 of clevis 90 with portion 81 of shaft 18. The durability is increased if the tolerance between portion 79 of clevis 90 and the interior bore of portion 81 of shaft 18 is close. Threads 74 may occur at any location along portion 79 of clevis 90, as long as the location of corresponding interior threads 76 of shaft 18 are adjusted accordingly. The fact that jaw assembly 30 and clevis 90 thread within interior threads in shaft 81 is advantageous. The threaded connection is protected from tissue, and the threaded connection, if metal, is easily electrically isolated from the surrounding environment. When actuating rod 28 has been fully inserted into shaft 18 and face 78 has securely engaged lip 75, if shaft 18 has been inserted into sleeve 50, connecting ball 72 may be caused to pass through a ball port 80 of rear handle 24 and into a quick-release port 82. A quick-release screw 84 may be threaded into a quick-release port 82 on a top portion of rear handle 24, securing ball 72 therein. According to a preferred embodiment, quick-release screw 84 is a captured screw. Once connecting ball 72 is secured within quick-release port 82, pivotal movement of rear handle 24 relative to front handle 12 results in longitudinal movement of actuating rod 28 within shaft 18, causing jaw assembly 30 to open and close. Such actuation is described more fully below.

It can be seen that actuating rod 18 and jaw assembly 30 may be interchanged with another actuating rod/jaw assembly

without removing the shaft, for example during a surgical procedure. Or, a shaft and actuating rod/jaw assembly may be replaced to shorten or lengthen the instrument, thus decreasing or increasing its reach.

Also illustrated in Fig. 2 is a removable use indicator 77 on jaw assembly 30. The presence of such a removable use indicator on any component of the present invention defines that component as a limited use component. This is described more fully below.

Referring now to Fig. 3, a quick-release feature according to one embodiment of the present invention is illustrated in detail showing connecting ball 72 of actuating rod 28 inserted through ball port 80 into quick release port 82 of rear handle 24. When quick release screw 84 is threaded into quick-release port 82 to the extent that it presses down upon ball 72, ball 72 is held firmly within port 82. Thus, screw 84 is moveable between a first, screwed position, securing ball 72 within port 82, and a second, unscrewed position allowing ball 72 to exit port 82 through port 80. The quick-release feature is a gimbal-like joint preventing axial movement of ball 72 relative to handle 24, but allowing rotation of ball 72 within port 82. According to a preferred embodiment, quick release screw 84 is a captured screw, and is caused to be retained within port 82 when unscrewed.

Fig. 4a is a top view of handle 24 according to another embodiment, illustrating a gimbal-like, quick-release feature according to another embodiment of the invention. In the embodiment illustrated in Fig. 4a, rear handle 24 includes an unthreaded quick-release port 86 and a slot 88, communicating with port 86 and a distal face 87 of handle 24. Fig. 4b is a cross-sectional side view through line 46-46 of Fig. 4a. Connecting ball 82 may slide into or out of port 86 through the top of handle 24, causing actuating rod ball 72 to be engaged or disengaged, respectively, by port 86. Slot 88 is of a width such that ball 72 is prevented from moving out of

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port 86 through the slot past face 87. Rear handle 24 must be removed from front handle 12 to effect engagement or disengagement of ball 72 with port 86 according to the embodiment illustrated in Figs. 4a and 4b, while such engagement and disengagement may be effected while handle 24 is attached to handle 12 according to the embodiment illustrated in Fig. 3.

Referring now to Fig. 5, a side view of disassembled jaw assembly 30 is illustrated and includes a clevis 90, including a top bracket 92 and a bottom bracket 94. Clevis 90 includes exterior threads 74 at a proximal end thereof, engaging interior threads 76 of shaft 18 (as illustrated in Fig. 2). As mentioned above, portion 79 of clevis 90 is designed to fit within the distal portion of shaft 18, adding stability to the shaft/jaw assembly connection, and exterior threads 74 may be positioned anywhere along portion 79. As also mentioned, it is advantageous if a relatively close tolerance exists between portion 79 of clevis 90 and the interior of shaft 18. Clevis 90 includes a longitudinal passageway 91 within which a distal portion of actuating rod 18 may pass, passageway 91 including a distal bore 96 and a proximal bore 98. Actuating rod 18 is mounted within bores 96 and 98, and a distal guide 100 of actuating rod 18 slides within distal bore 96, having a relatively close tolerance therewith. One or more cleaning holes 93 may be provided in clevis 90, communicating with passageway 91 to provide better cleaning of passageway 91 and portions of actuating rod 18 in passageway 91. Cleaning holes 93 are covered by shaft 18 during use of instrument 10. Therefore, holes 93 do not collect tissue during instrument use. However, holes 93 are provided so that, in the event that any material becomes trapped within passageway 91, it is easily removed.

First jaw member 32 and second jaw member 34 are mounted within top and bottom brackets 92 and 94 of clevis 90, jaw member 34 being mounted above jaw member 32. A hinge pin 102 passes through hinge pin holes 104 and 106 of top and bottom

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brackets 92 and 94, respectively, and passes through a hinge hole 108 of second jaw member 34 and a hinge hole 110 of first jaw member 32. Hinge pin 102 fits snugly within hinge pin holes 104 and 106, such as by a friction fit, welding, adhesive, or the like. Pin 102 has a diameter slightly smaller than hinge holes 108 and 110 of jaw members 34 and 32, thus the jaw members may freely pivot thereabout. An actuating rod pin 110, secured to actuating rod 18, rides within an actuating slot 112 of jaw member 32 and an actuating slot 114 of jaw member 34, and causes the jaw members to open and close, as described more fully below. Actuating pin 110 may be friction fitted, welded, fastened with adhesive, or otherwise securely fastened to rod 18. Alternatively, according to a preferred embodiment, pin 110 is integral with actuating rod 18. When pin 110 is integral with rod 18, increased structural integrity and durability of the entire jaw assembly results. Additionally, distal guide 100 of actuating rod 18 may or may not be integral with more proximal portions of rod 18. If guide 100 is not integral with more proximal portions of rod 18, the more proximal portions of rod 18 may thread into guide 100. Similarly, guide 100 may or may not be integral with more distal portions of rod 18. For purposes of description, rod 18 includes guide 100 and more proximal portions.

Referring now to Fig. 6, a top view of disassembled jaw assembly 30 is illustrated. As illustrated, jaw members 32 and 34 are serrated graspers. However, the particular type of jaw member is not important to the present invention, and a wide variety of tools may be selected, for example dissectors, dolphin-nose dissectors, Maryland dissectors, scissors, graspers, Metzenbaum shears, micro shears, fenestrated forceps, or the like.

Jaw members 32 and 34 are designed and constructed so as to be durable, and to provide significant grasping or cutting force. To provide significant grasping or cutting force, significant torque must be generated about pin 110. This is

especially important when instrument 10 is used to cut or dissect through particularly thick or tough tissue, or is used to grasp a particularly thick portion of tissue with significant force. In such a situation, to achieve adequate torque, the distance between the center of pin 110 and a proximal end 115 of actuating slot 112, represented by dimension x, relative to the distance between the center of pin 110 and a distal end 117 of jaw member 32, represented by dimension y, should be of at least a minimum ratio. Stated another way, a lever portion of jaw member 32, represented by that portion of jaw member 32 falling within dimension x, relative to a working portion of jaw member 32, represented by that portion falling within dimension y, should be of at least a minimum ratio. In such situations where significant grasping strength is required, the ratio of dimension x to dimension y should be less than 1:8, preferably less than 1:4.5, more preferably from about 1:1 to about 1:3.5, and more preferably still from about 1:2 to about 1:3.

Also illustrated in Fig. 6 is use indicator 77. Use indicator 77 includes one or more visible indicators, one or more of which may be removed or changed during the occurrence of a procedure to which the instrument is subjected, the lifetime of the instrument being defined by a predetermined number of such procedures. The procedures may include use of the instrument, sterilization, or, preferably, both. For example, as illustrated in Fig. 6, the numbers, "1," "2" and "3" may be laser-written into the side of clevis 90 or may be etched or printed therein according to another mechanism. The individual numbers may be removed after the procedure, such as via abrasion. For example, a blade, file, or any hard object may be used to score or mark one of the numbers, after a procedure, in any way that makes it distinguishable from other numbers, or from its condition prior to marking. Alternately, the indicator may be selected so as to be chemically or physically reactive to a particular sterilization step, and may automatically be ablated serially

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by these steps. For example, the numeral "1" may be ablated automatically after 1 sterilization the numeral "2" being ablated after two sterilizations; and the numeral "3" being ablated after 3 sterilizations. Other, non-limiting examples of use indicators suitable for use with the present invention include a colored strip or strips, the color of which, or the location of a particular color change along a strip, is indicative of the number of procedures to which the instrument has been subjected; a punch out system, allowing a user to physically alter the dimension of or remove a plug of material to denote use; application of paint, plastic, metal or other material that could be removed to indicate use; and mechanical means that could be manually advanced or automatically advanced to indicate use.

Although indicator 77 is illustrated on clevis 90 only, it may be advantageously provided on any component of the instrument that is designed to be of limited use. It may be provided at any location, including those locations hidden from view when the instrument is assembled. In this way, the component bearing the indicator is truly a limited use component by definition, as the number of procedures to which the component has been subjected is registered on a record that is not removable from the component. An advantage associated with an instrument that is of limited use by definition is that components of an instrument which must always be sharp or aligned, or components which should be replaced regularly to avoid dangerous material fatigue, may be marked with a removable use indicator. Fatigue may be caused by use or by sterilization, or both. Reusable components of the invention need not be so marked, and if all the components are interchangeable, there is no need for return of an entire instrument for repair if one particular component is damaged or needs to be sharpened, and the instrument may be continually used indefinitely, with a minimum of service cost and a maximum of safety.

Use indicator 77 may designate the number of uses or procedures to which the instrument or component of the instrument has been subjected, or the number of uses or procedures of the instrument or component of the instrument that may yet be carried out. Additionally, more than one use indicator may reside on any component. For example, a component may bear a use indicator that comprises marks that must be physically altered by an operator when the operator so wishes, and may also include an automatic indicator, such as a color indicator, indicating the number of a particular procedure to which the component has been subjected. In this way, and as an example, a particular component may bear automatic indication of the number of times it has been sterilized, and bear marks which may be physically altered in some way by an operator, indicating the number of a particular procedure to which the component has been subjected, or the number of such procedures to which the component may be subjected prior to the end of the component's useful life. This may find special use when a particular component may be subjected to a particular number of a first procedure, or a particular number of a second procedure, but not both. For example, the useful life of a particular component may be defined by ten sterilizations, or three uses, but not both. In such a situation, the component would advantageously bear a indicator of the number of sterilizations, and an indicator of the number of uses.

In many circumstances, it is an advantage if an indicator of the number of procedures to which the instrument or component has been subjected is not automatic, but is manually tallied. In this way, an operator may make a decision regarding whether an instrument or component has indeed been subjected to the predetermined procedure. Thus, a use is not tallied by assembly or disassembly of the instrument, or removal from packaging, or preparation for surgery, if the instrument is not used and has not suffered any wear which should be tallied as one use.

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Referring now to Figs. 7 and 8, assembled jaw assembly 30 is illustrated, and the operation thereof is explained. When front handle 12 and rear handle 24 are squeezed together by the hand of an operator (reference may be made to Fig. 1) actuating rod 28 is caused to move longitudinally within shaft 18 in a proximal direction relative thereto. As shaft 18 is secured to clevis 90 during instrument operation, shaft 18 also moves proximally relative to clevis 90 when the handles are squeezed together. Referring first to Fig. 8, this causes actuating pin 110 to exert a force, including a central component, on each of actuating slots 114 and 112 of jaw members 34 and 32, respectively, exerting a central force on portions of jaw members 32 and 34 proximal relative to hinge pin 102. By lever action, this exerts a central force on portions of jaw members distal relative to hinge pin 102, and the jaws are closed, as illustrated in Fig 7.

When front handle 12 and rear handle 24 are caused to be separated, actuating rod 18 is caused to move longitudinally within shaft 28 in a distal direction relative to shaft 28 and clevis 90. Referring to Fig. 7, this causes actuating pin 110 to exert a force, including a lateral component, on each of actuating slots 112 and 114, exerting a lateral force on portions of jaw members 32 and 34 proximal relative to hinge pin 102. By lever action, this exerts a lateral force on portions of jaw members distal relative to hinge pin 102, and the jaws are opened as illustrated in Fig 8.

When actuating pin 110 reaches distal ends of actuating slots 112 and 114, it is stopped, in part by the distal ends of the slots, and the jaws are maximally opened. Additionally, at that point, actuation stop faces 120 and 122 of jaw members 32 and 34, respectively, are caused to abut pin 110. Thus, when jaw assembly 30 is completely open, hinge pin 110 is stopped from distal movement by actuating slots 112 and 114, and by actuation stop faces 120 and 122. This adds considerable durability to the overall jaw assembly. Additionally, the overall jaw assembly is durable

due to the actuation design, in which, when actuation is effected so as to open or close the jaws, any lateral or central force on any jaw component is balanced by an equal and opposite lateral or central force on another jaw component, respectively.

Referring now to Fig. . . a modified ratchet mechanism according to one embodiment of the invention is illustrated, provided at proximal end 13 of instrument 10. The mechanism is operable by providing a ratchet stop, or impinger 124 mounted on front handle 12 and moveable from a first position to a second position via actuation of a trigger 126. Trigger 126 is positioned so as to be easily addressable by a surgeon while he or she is holding the instrument normally.

A ratchet piece, or impinging member 128 is attached to front handle 24 by fastening means such as a bolt 125, and includes a ratchet hole 130, within which actuating rod 18 rides. Ratchet piece 128 has a portion 129 that rests against a rear face of ratchet stop 124 when stop 124 is in the unratched position illustrated in Fig. 9. According to the embodiment illustrated, ratchet piece 128 is a substantially planar, somewhat flexible member, formed of metal, plastic, or the like. According to a preferred embodiment, ratchet piece 128 is formed of a thin strip of surgical stainless steel. In an unratched position, piece 128 is held nearly perpendicular to actuating rod 18. In this position, actuating rod 18 may freely slide through hole 130 of piece 128. When trigger 126 is pushed forward so as to shift ratchet stop 124 to a ratched position, as illustrated in Fig. 10, ratchet piece 128 is permitted free movement, and when actuating rod 18 is urged distally, it causes end 129 of piece 128 to be urged distally, causing hole 130 to engage rod 18 and to prevent such distal movement. Hole 130 engages rod 18 primarily at the top and bottom of the hole in this case. Thus, when the jaw member firmly grasps an object and ratchet stop 124 is moved to the ratched position illustrated in Fig. 10, ratchet piece 128

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prevents distal movement of actuating pin 18 and the jaws are not permitted to open. It is a feature of the inventive ratchet mechanism that rod 18 may be prevented from distal movement by engagement of the ratchet, at any location on a continuum within the free longitudinal travel of rod 18 within hole 130.

Referring now to Fig. 11, a perspective view of a handle assembly according to the embodiment illustrated in Fig. 1 is shown in detail. According to the embodiment illustrated, front handle 12 is integral with shaft mount 15. Alternatively, shaft mount 15 may be removably attached to front handle 12. Shaft mount 15 mounts shaft 18 (illustrated in Fig. 1) by way of threaded coupling between a threaded portion 17 of shaft mount 15 and bee nut 20 of shaft 18 (illustrated in Fig. 1).

Actuating rod 28 is operably coupled to rear handle 24, so as to move longitudinally in the directions of arrow 238 when rear handle 24 is pivoted relative to front handle 12. Specifically, when the handles are opened, that is, when finger holes 14 and 25 are separated, rod 28 moves distally within shaft 18 and causes a surgical tool to be moved to a particular position. For example, the instrument may be arranged such that when the handles are opened jaw assembly 30 is opened. When the handles are closed, rod 28 moves proximally within shaft 18 and causes, for example, jaw assembly 30 to be closed.

Fig. 11 illustrates a modified ratchet mechanism according to another embodiment of the invention. Impinging member 240 is movably mounted within a bore passing through a wall of shaft mount 15, and trigger 242 is secured to impinging member 240 so as to move therewith. According to the embodiment illustrated, trigger 242 pivots at impinging member 240 between an unlocked position in which rod 28 is free to move axially in the directions of arrow 238, and a locked position in which impinging member 240 secures actuating rod 28 against movement. Specifically, trigger 242

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may be pivoted distally, in the direction of arrow 244, to the unlocked position and may be pivoted proximally, in the direction of arrow 246, to the locked position. Trigger 242 is designed and positioned so as to be easily manipulated by an operator of the surgical instrument. An operator can easily manipulate trigger 242 with his or her index finger while holding the instrument normally, with one hand, by the handles 12 and 24.

Trigger 242 may take a variety of shapes, as will be discussed more fully below. Fig. 12 illustrates trigger 242 according to one alternate embodiment. According to the embodiment illustrated in Fig. 12, trigger 242 is positioned further distally relative to front handle 12 than it is positioned according to the embodiment illustrated in Figs. 1 and 11.

The operation of an impinging member according to one embodiment of the present invention will now be described with reference to Fig. 13, which is a cross-section through line 13-13 of Fig. 11. Referring to Fig. 13, shaft mount 15 includes longitudinal passage 246, through which actuating rod 28 (not shown) passes. Shaft mount 15 also includes bore 248, substantially perpendicular to passage 246 and passing through a wall 251 of the shaft mount to passage 246. Impinging member 240 includes a substantially cylindrical shaft mount portion 250 mounted within bore 248, and a substantially cylindrical trigger portion 252 protruding from bore 248 and wall 251. Shaft mount portion 50 of impinging member 240 terminates in impinging surface 254, which is approximately tangential to the outside diameter of passage 246. Passage 246, in the vicinity of impinging member 240, has a diameter slightly larger than the outside diameter of a portion of rod 28 adjacent impinging member 240. Thus, the impinging member is mounted adjacent the actuating rod.

Trigger 242 includes a bore 256, in which trigger portion 252 of impinging member 240 is mounted. Trigger portion 252 may be secured within bore 256 by any of a wide variety of

connections known to those skilled in the art. For example, portion 252 may be press-fitted within bore 256. According to this embodiment, portion 252 may be knurled.

Alternatively, portion 252 may be threadingly coupled to bore 256, or an allen screw or other screw may pass through trigger 242 and impinge upon portion 252. According to the latter embodiments trigger 242 may be interchanged with other triggers of, for example, different shape.

Bore 248 in shaft mount 15 includes an interior threaded surface, and shaft mount portion 250 of impinging member 240 has corresponding threads. Accordingly, when trigger 242 is moved distally or proximally, that is, when trigger 242 is pivoted with impinging member 240 within bore 248 of shaft mount 15, impinging member 240 moves laterally in one of the directions of arrow 258. The direction of lateral movement of impinging member 240 upon movement of trigger 242 depends upon the threading of bore 248 and shaft mount portion 250 of the impinging member. According to a preferred embodiment, right-handed threaded coupling is provided between bore 248 and portion 250, thus movement of the trigger proximally, into a locked position (in the direction of arrow 246 in Fig. 11) causes impinging member 240 to move further into bore 248, and movement of the trigger distally, into an unlocked position (in the direction of arrow 244 in Fig. 11) causes impinging member 240 to move in a direction out of bore 248.

Shaft mount portion 250 of impinging member 240 terminates in impinging surface 254, which is approximately tangential with the substantially cylindrical border defining passage 246 adjacent the impinging member. Specifically, impinging member 240 is threadingly mounted within bore 248 such that when actuating rod 28 is carried within passage 246 and trigger 242 is moved distally, impinging surface 254 is positioned so as to allow rod 28 to freely move axially within shaft mount 15 (in the directions of arrow 238 of Fig. 11). When trigger 242 is moved proximally, impinging surface

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254 impinges upon rod 28, securing the rod against axial movement.

According to a particularly preferred embodiment, shaft mount portion 250 of impinging member 240 and bore 248 include 32 threads per inch. Thus, impinging surface 254 moves laterally in the directions of arrows 258 approximately 0.008 inch between the locked and unlocked positions of the modified ratchet, that is, between the most proximal and most distal positions of the trigger. However, the number of threads per inch may be widely varied in accordance with the invention to provide greater or lesser travel of impinging surface 254 upon movement of the trigger. For example, the instrument may be designed such that impinging surface 254 moves laterally from the locked to the unlocked positions a distance of from about 0.003 to about 0.018 inch, preferably from about 0.005 to about 0.014 inch, and more preferably from about 0.006 to about 0.011 inch.

Impinging surface 254 may take a variety of shapes. For example, surface 254 may be flat, rounded, cupped, grooved, or may be chamfered in a variety of ways. Surface 254 may be shaped so as to conform to the surface of actuating rod 28 when in the unlocked position, and so as not to conform to the surface of rod 28 when in the locked position. According to the latter embodiment, impinging member 240 need not be threadingly mounted within bore 256 of shaft mount 15. That is, impinging member 240 may rotate within bore 256 upon movement of trigger 242, but not move laterally in a direction of arrow 258, whereupon surface 254 may move from an orientation in which it conforms to the surface of rod 28 to an orientation in which it does not conform to the surface of rod 28 and impinges upon the rod, securing it against axial movement.

Bore 248 may pass through a wall of shaft mount 15 at any of a variety of positions, as long as it can carry impinging member 240 in a position relative to passage 246 such that impinging surface 254 may be positioned so as to secure

actuating rod 28 against axial movement. For example, bore 248 may pass through the top of shaft mount 15. According to this embodiment impinging member 240 will protrude from the top of shaft mount 15, and trigger 242 will be pivotally mounted atop the shaft mount. In such a case trigger 242 would advantageously have a depending portion passing beside shaft mount 15 so as to be most easily accessible by the index finger of operating personnel. Bore 248 may also be created through the bottom of shaft mount 15, with an associated impinging member protruding from the bottom of mount 15 and a trigger mounted on the impinging member.

According to the embodiment illustrated in Fig. 13, trigger 242 includes a indexing portion 260 passing beneath shaft mount 15 and extending laterally both to the right and to the left of the shaft mount. Indexing portion 260 is thus easily manipulated by the index finger of left-handed as well as right-handed operating personnel.

As illustrated, impinging member 240 is unitary, that is, shaft mount portion 250 is integral with trigger portion 252. However, impinging member 240 may comprise a plurality of components, for example a shaft mount portion secured to a trigger portion.

Referring now to Fig. 14, an embodiment of the invention is illustrated in which a second impinging member 262 is mounted in a second bore 264 in a wall 66 of shaft mount 15. Second impinging member 262 is approximately identical to impinging member 240, and second wall 266 is opposite wall 251. Thus, impinging surface 254 and a second impinging surface 268 of second impinging member 262 are each positioned approximately tangential the circumference of passage 246. A trigger 270 according to this embodiment is mounted upon impinging member 240, passes beneath shaft mount 15, and is mounted on the opposite side of shaft mount 15 on second impinging member 262. Preferably, second impinging member 262 and second bore 264 have threads opposite those of impinging member 240 and bore 248, so that when trigger 270

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is moved into the locked position, impinging surfaces 254 and 268 both impinge upon actuating rod 28 (not shown in Fig. 14). Trigger 270 must have sufficient flexibility to tolerate opposing lateral movement of impinging members 240 and 262 according to this embodiment. Alternatively, trigger 270 may be mounted upon impinging members 240 and 262 so as to be movable laterally relative to each. For example, a laterally slotted fitting between the trigger bores of trigger 270, and impinging members 240 and 262, may be provided.

Referring now to Fig. 15, an embodiment of the invention is illustrated in which an impinging member is cammingly caused to impinge upon actuating rod 28. Specifically, the embodiment illustrated includes shaft mount 15 including a bore 272 extending from wall 251 into the shaft and terminating at interior bore end 274. Bore 272 includes an interior portion 276, terminating at bore end 274 and within which an impinging member 278 is carried, and a threaded portion 280 between the interior portion and wall 251, within which a cam impinger 282 is threadingly engaged. Cam impinger 282 includes a threaded portion 284 threaded within threaded portion 280 of bore 272 and a portion 286 protruding from bore 272 and from wall 251 and mounting trigger 242 as described above.

Impinging member 278 includes a passage 287 within which actuating rod 28 (not shown) rides. A resilient member 285, such as a spring, is mounted between interior bore end 274 and a terminus of impinging member 278, urging member 278 in the direction of wall 251. Impinging member 278 terminates at an end opposite that of the resilient member in an impinging member cam surface 286, which abuts an impinger cam surface 288 of the cam impinger 282. Thus, impinging member 278 is urged toward wall 251 by resilient member 285 and held within bore 272 by cam impinger 282. Impinging member 278 is secured against rotation within bore 272 by way of, for example, laterally slotted engagement with bore 272.

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When trigger 242 is moved from the unlocked position into the locked position, cam impinger 282 rotates within threaded portion 280 of bore 272, and is urged into the bore.

Impinger cam surface 288 of cam impinger 282 rotates relative to impinging member cam surface 286 of impinging member 278. the resultant camming engagement urging impinging member 278 into bore 272 to a greater extent than impinger 282 is threaded into bore 272. The border defining passage 287 then moves laterally in a direction into bore 272, and engages actuating rod 28, securing it against axial movement.

The embodiment described with reference to Fig. 15 provides both threading engagement and camming engagement to urge impinging member 278 laterally so that the border defining passage 287 engages actuating rod 28. According to alternate embodiments, either of the threading or camming engagement may be separately utilized.

According to one alternate embodiment, similar to that illustrated in Fig. 15, surfaces 286 and 288 of impinging member 278 and impinger 282, respectively, are flat rather than cammed. When impinger 282 is rotated within bore 272 by trigger 242, it is threaded laterally into the bore. Surface 288 exerts a force on surface 286 of the impinging member 278, urging the impinging member laterally, whereupon the border defining passage 287 engages rod 28.

According to another alternate embodiment, similar to that illustrated in Fig. 15, cam impinger 282 is mounted within bore 272 and rotatable therein by trigger 242, but is not threadingly mounted within the bore. Accordingly, when the cam impinger is rotated upon movement of the trigger, it does not move laterally relative to the bore, but the camming engagement described above ensues, securing actuating rod 28 by lateral movement of impinging member 278.

Another embodiment of the present invention is illustrated in Fig. 16, and includes shaft mount 15 defining passage 246 through which actuating rod 28 (not shown in Fig. 16) passes. An impinging member 290 passes through a bore

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292 extending entirely through shaft mount 15. Bore 292 passes below passage 246, substantially perpendicularly thereto, and overlaps passage 246 slightly. Impinging member 290 includes a portion 294 which protrudes from wall 251 of the shaft mount and mounts trigger 242 as described above, and an expanded portion 296 which protrudes from a wall opposite wall 251 and which retains the impinging member in bore 292. Impinging member 290 includes a cut-out providing a surface 298 which conforms to the dimension of the border defining passage 246 where the impinging member overlaps passage 246, when trigger 242 is in the unlocked position. Thus, in the unlocked position actuating rod 28 (not shown in Fig. 16) is free to move axially within passage 246 past the adjacent surface 298 of impinging member 290. When trigger 242 is moved into the locked position, impinging member 290 is rotated within bore 292, conforming surface 298 is rotated away from actuating rod 228, and impinging member 290 fills bore 292 at its overlap with passage 246. Thus, and impinging member 290 impinges upon rod 28, securing it from axial movement. The position of impinging member 290 within passage 246 in the locked position is represented by dotted line 300.

The depth of the cut-out defining conforming surface 298 may take a variety of dimensions. Preferably, the depth of the cut-out, that is, the clearance between conforming surface 298 and dotted line 300, is from about 0.009 to about 0.029 inch, more preferably from about 0.014 to about 0.024 inch, and most preferably from about 0.017 to about 0.021 inch. According to a particularly preferred embodiment the dimension is 0.019 inch.

Yet another embodiment of the present invention in which an impinging member is cammingly caused to impinge upon actuating rod 28 is illustrated in Fig. 17. Specifically, the embodiment illustrated includes shaft mount 15 including a bore 302 extending from wall 251 into the shaft and terminating at interior bore end 304. Bore 302 includes an

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interior portion 306, terminating at bore end 304 and within which an impinging member 308 is carried. Impinging member 308 includes a passage 309 within which actuating rod 28 (not shown) rides. Bore 302 also includes a slotted portion 310 between the interior portion 306 and wall 251 including slots 312 within which tabs 314 of impinging member 308 ride. Impinging member 308 may move longitudinally within bore 302 but is prevented from rotation within the bore by the tabs 314 within slots 312. Impinging member 308, when inserted completely within bore 302, does not completely fill bore 302 but terminates short of wall 251 at shoulder 309 so as to define a void 311 between the shoulder 309 and wall 251.

A ramp 316 is mounted on wall 251 of shaft mount 215 such that a bore 318 within the ramp is coaxial with bore 302. Ramp 316 may be soldered to shaft mount 15, brazed thereto, fastened with adhesive, screws, rivets or the like, or may be integral with shaft mount 15. Ramp bore 318 has a diameter smaller than that of bore 302, thus ramp 316 defines a shoulder 315 that is flush with wall 251. A resilient member 313 such as a spring or the like may be mounted between ramp shoulder 315 and shoulder 309 of impinging member 308, urging the impinging member into bore 302.

Ramp 316 includes a ramp or cam face 320 facing away from the shaft mount. Impinging member 308 includes a shaft 317 that protrudes from bore 302 and through bore 318 of ramp 316. Shaft 317 is integral with impinging member 308, or is secured to impinging member 308 so as not to be rotatable relative thereto. Trigger 322 includes a bore 324 and a trigger ramp or cam face 326 and is mounted such that shaft 317 of impinging member 308 passes through bore 324 and supports the trigger, and trigger ramp face 326 is held adjacent ramp face 320. Impinging member shaft 317 passes completely through trigger bore 324 and protrudes from a side of the trigger opposite the trigger ramp face 320, where it is fastened to a capturing device such as a bolt 326.

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Trigger 322 is mounted upon and may rotate relative to shaft 317 of impinging member 308. When trigger 322 is manipulated by an operator of the surgical instrument so as to rotate relative to shaft 317, it is made also to rotate relative to ramp 316. Thus, such manipulation causes trigger ramp face 326 to rotate relative to ramp face 320, causing trigger 322 to move laterally away from ramp 316 and shaft mount 15. Trigger 322 exerts a lateral force upon capturing device 326, hence upon shaft 317 and impinging member 308, whereupon resilient member 313 is compressed between impinging member shoulder 309 and ramp shoulder 315. This causes passage 309 to be moved laterally, whereupon the border defining passage 309 impinges upon actuating rod 28 (not shown), securing it against axial movement.

According to an alternate embodiment similar to that illustrated in Fig. 17, shaft 317 is rotatably coupled to impinging member 308 such as by a bearing or the like. According to this embodiment, impinging member shaft 317 may be secured to trigger 322 so as to rotate therewith.

Although resilient member 313 is mounted between impinging member shoulder 309 and ramp shoulder 315 according to the embodiment illustrated, a resilient member may alternatively or additionally be mounted between interior end 304 of bore 302 and the interior end of impinging member 308 so as to resiliently retain impinging member 308 within bore 302.

Although not illustrated in any of the accompanying figures, washers or bearings may be provided between components of the modified ratchet assembly of the present invention that are designed to move relative to each other. Additionally, although in some of the embodiments illustrated a resilient member urges an impinging member in a direction into or out of a bore in the shaft mount to position the impinging member in the unlocked position, according to alternate embodiments no resilient member is provided and the

impinging member is held in the unlocked position by the actuating rod.

As is apparent from the description above, the impinging member of the present invention may engage the actuating rod or the instrument at any of a continuum of locations along the path of travel of the rod past the impinging member. Thus the rod, hence the surgical tool, may be secured at any location within its range of travel, rather than only at particular locations such as those that would be provided by a typical toothed ratchet. Thus, the impinging member and trigger of the present invention are referred to herein as a modified ratchet mechanism.

Components of the present invention may be fabricated from sterilizable, durable material such as surgical stainless steel or another metal, alloy, or durable composite. According to embodiments including electrode 66, an electrically-insulating material coats portions of instrument 10 that are advantageously electrically isolated from electrode 66 and/or jaw members 30. For example, an electrically insulating material may coat shaft 18, star wheel 36, bee nut 20, front and rear handles 12 and 24, thumb screw 38, quick release screw 84, and trigger 242. Such electrically insulating material may take the form of shrink wrap, or spray-on insulators such as the commonly-known material Kynar®. According to one embodiment, handles 12 and 24 and trigger 242 are not coated with electrically-insulating material.

As is apparent from the above description, with reference to the accompanying drawings, instrument 10 is constructed so that various components are replaceable by components performing different functions, or performing the same function in a different manner. For example, front handle 12 bearing electrode 66 may be replaced by a front handle 12 absent of electrode 66. Or, a front handle having a modified ratchet may be substituted for a front handle not having a ratchet. According to the embodiments illustrated, front

handle 12 having ratchet stop 124 would be incompatible with a front handle having an electrode. However, according to embodiments not illustrated, electrode 66 may address sleeve 50, and thus shaft 18, via a pathway other than port 68, the pathway being compatible with the presence of ratchet stop 124. Additionally, shaft 18, actuating rod 28, and jaw assembly 30 may all be replaced by another, similar assembly of a different length for having a jaw assembly designed to perform a different function. Alternately, jaw assembly 30 may be removed from shaft 18 without removing shaft 18 from front handle 12, so as to replace jaw assembly 30 with one performing a different function. Removal of jaw assembly 30 and rod 28 from the instrument, or removal of jaw assembly 30, rod 28, and shaft 18 from the instrument may be quickly effected by unscrewing quick-release screw 84 from rear handle 24, or, according to the embodiment illustrated in Figs. 4a and 4b, unscrewing of thumb screw 38 and removal of rear handle 24 from front handle 12.

It can be seen that replacement of various instrument components may be quickly done in a safe manner. That is, replacement of any instrument components may only be effected by manipulation of a fastener at proximal end 13 of instrument 10, such as quick-release screw 84 or thumb screw 38. Additionally, quick-release screw 84 and thumb screw 38 may be captured screws, thus when the instrument is disassembled, no small fasteners may be lost or dropped.

It is a feature of the present invention that when instrument 10 is assembled, actuating rod 28/jaw assembly 30 is secured within the instrument at more than one location, specifically, by threading exterior threads of clevis 90 into interior threads 76 of shaft 18, and the coupling of ball 72 within port 82 of rear handle 24. Such a design minimizes the likelihood that instrument 10 may be accidentally disassembled, especially minimizing the likelihood that jaw assembly 30 may become removed from the instrument within a patient.

It is another feature of the present invention that the inventive instrument may be disassembled for easy cleaning. Problems associated with flush ports of heretofore known instruments are thus avoided, and the inventive instrument may be much more easily thoroughly cleaned than instruments that can not be disassembled easily.

As used herein, the term "secure", with reference to attachment of various components of the instrument to other components, is meant to define a means of attachment that does not easily become accidentally unattached. With reference to Fig. 2, it can be seen that jaw assembly 30, via clevis 90 and in particular clevis threads 74, securely attaches to the distal portion of shaft 18 when threads 74 engage interior threads 76 of the shaft. Jaws 32 and 34 may advantageously be opened during such attachment, so that the operator may achieve maximum torque in engaging the threads. When lip 75 of assembly 30 tightly abuts face 78 of shaft 18, secure attachment is achieved. This attachment is not easily accidentally unattached, as, for such an event to occur, the jaw assembly would necessarily unscrew through many rotations. This would be unlikely if the jaw assembly were in use, and were open during much of the time while in contact with surrounding tissue. Secure attachment is achieved between rod 28 and rear handle 24 through the coupling of ball 72 in port 82, as described with reference to Figs. 3, 4a, and 4b. According to the embodiment illustrated in Fig. 3, ball 72 is secured when thumb screw 84 is securely threaded onto the ball. In the embodiment illustrated in Figs. 4a and 4b, ball 72 may not exit port 86 unless rear handle 24 is unattached from front handle 12. Such secure attachment at critical junctions of the instrument is important so that accidental unattachment does not occur. As illustrated, such secure attachment takes the form of fasteners such as threaded coupling, and a gimbal-like joint. However, other means of secure attachment are within the scope of the present invention, for example a

ramp lock, or the like. According to one embodiment, all such fasteners on instrument are captured. As used herein, the term "captured fastener" is meant to define a fastener that may be unfastened without removal of the fastener from a component of the instrument. This includes a captured screw, a ramp lock, or any other type of such fastener. For example, with reference to Fig. 2, a ramp lock or the like could fasten rear handle 24 to front handle 12, fasten jaw assembly 30 to shaft 18, fasten shaft 18 to front handle 12, fasten proximal end of rod 28 to rear handle 24, etc. These and other captured fastening means are within the scope of the invention. Additionally, the term "secure", as used herein, is meant to define an attachment made by an operator which, when it is secure, indicates this to the operator. For example, in the threaded engagement between jaw assembly 30 and shaft 18, it is apparent to the operator that such assembly is secured when lip 75 firmly engages face 78. When thumb screw 84 is screwed to engage ball 72 within port 82, it is apparent to the operator when secure coupling has been effected.

It is another feature of the present invention that instrument 10 is designed so that all portions of the instrument, with the exception of portions designed to be in electrical communication with tissue, may be completely coated with electrical insulation.

Those skilled in the art will readily appreciate that all parameters listed herein are meant to be exemplary and that actual parameters will depend upon the specific application for which the inventive surgical instrument is being used. For example, although grasping forceps are exclusively illustrated in the description above, serrated jaws, scissors, graspers, electro-cauterization apparatus, and the like may replace jaws 30. Additionally, although only two cleaning openings are illustrated and described with respect to the embodiment of the invention illustrated above, a plurality of cleaning openings may be provided on a variety

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of instrument components. As would be apparent to one of ordinary skill in the art, according to one aspect the invention resides in the provision of an impinging member which may be easily moved by a surgeon into a position engaging an actuating rod of a minimally-invasive surgical instrument, such that the rod may be secured at any of a continuum of locations. The surgical instrument may take the form of an arthroscopy instrument, a laparoscopic instrument, or the like, and includes a surgical tool operably linked to an actuator which is in turn operably linked to surgical tool. The tool may be manipulated by a surgeon so as to control the surgical tool. The tool mechanism may be the handle itself, or may be a separate trigger or the like on the portion of the instrument remaining outside of the patient during surgery. It is, therefore, to be understood that the foregoing embodiments are presented by way of example only and that, within the scope of the appended claim and the equivalents thereto, the invention may be practiced otherwise as then is specifically described.

What is claimed is:

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CLAIMS:

1. A minimally-invasive surgical instrument comprising:
a shaft having a proximal end and a distal portion, said
distal portion residing within a patient during surgery and
said proximal end residing outside of the patient, said
distal portion securable to a surgical tool movable between a
first and a second operating position;

A tool-manipulator secured to said proximal end of said
shaft and movable between a first and a second
tool-manipulator position;

an actuator associated with said shaft and movable
between a first and a second actuator position, said actuator
operably linked to said tool-manipulator and operably
linkable to said surgical tool to effect movement in said
tool between said first and second operating positions when
said tool-manipulator is moved between said first and second
tool-manipulator positions, respectively; and

an impinging member mounted adjacent said actuator on one
of said proximal end of said shaft or said tool-manipulator,
and movable between a first impinging member position in
which said actuator is freely movable between said first and
second actuator positions, and a second impinging member
position engaging said actuator and securing said actuator
against movement between said first and second actuator
positions.

2. The surgical instrument as recited in claim 1, and
further comprising a handle secured to said proximal end of
said shaft wherein said impinging member is mounted adjacent
said actuator on one of said proximal end of said shaft, said
handle, or said tool-manipulator.

3. The surgical instrument as recited in claim 2,
wherein said tool-manipulator comprises said handle, and said
handle is movable between a first and a second handle
position defining said first and second tool-manipulator
positions.

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4. The surgical instrument as recited in claim 1, wherein said impinging member is positioned adjacent any of a continuum of locations on said actuator between a first and a second point when said actuator moves between said first and second actuator positions, and is movable between said first impinging member position and said second impinging member position engaging said actuator at any of said continuum of locations and preventing said actuator from movement.

5. A minimally-invasive surgical instrument comprising:
a shaft;
a surgical tool secured to said shaft and movable between a first and a second operating position;
a handle secured to said shaft, spaced from said surgical tool and movable between a first and a second handle position;
an actuator associated with said shaft and movable between a first and a second actuator position, said actuator operably linked to said handle and operably linkable to said surgical tool to effect movement in said tool between said first and second operating positions when said handle is moved between said first and second handle positions, respectively; and
an impinging member mounted adjacent said actuator and movable between a first position in which said actuator is freely movable between said first and second actuator positions, and a second position engaging said actuator and securing said actuator against movement between said first and second actuator positions.

6. A minimally-invasive surgical instrument comprising:
a shaft;
a handle secured to said shaft;
a surgical tool secured to said shaft and spaced from said handle; and
an indicator on at least one of said shaft, said handle member, or said surgical tool, indicating the status with

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respect to useful life, of said shaft, said handle member, or said surgical tool.

7. The surgical instrument as recited in claim 6, wherein said indicator is located on said surgical tool.

8. The surgical instrument as recited in claim 6, wherein the status of said shaft, said handle member, or said surgical tool may be determined by viewing said indicator with the naked eye.

9. The surgical instrument as recited in claim 6, wherein said indicator comprises a plurality of indicia, each of which may be altered by an operator so as to be distinguishable from an unaltered state.

10. The surgical instrument as recited in claim 6, wherein said indicator comprises a material providing a first indication prior to a sterilization step and automatically providing a second indication distinguishable from the first indication subsequent to the sterilization step.

11. The surgical instrument as recited in claim 6, wherein said indicator is positionable in a first position and a second position distinguishable from the first position.

12. The surgical instrument as recited in claim 6, wherein said indicator comprises a mark made by an operator of the instrument.

13. A method of indicating status, with respect to useful life, of a minimally-invasive surgical instrument component, the method comprising:

providing a minimally-invasive surgical instrument including a shaft, a handle secured to the shaft, and a

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surgical tool secured to the shaft and spaced from the handle;

employing the minimally-invasive surgical instrument in a procedure; and

indicating the status on one of the shaft, the handle, or the surgical tool.

14. The method as recited in claim 13, wherein said indicating step comprises making a mark on one of the shaft, the handle, or the surgical tool.

15. The method as recited in claim 14, wherein the mark comprises a symbol visible to the naked eye.

16. The method as recited in claim 13, wherein said indicating step comprises moving a positionable indicator from a first position to a second position.

17. The method as recited in claim 13, wherein said indicating step comprises altering a mark on one of the shaft, the handle, or the surgical tool in a way that the mark is distinguishable from an unaltered state.

18. The method as recited in claim 13, wherein said indicating step comprises exposing one of the shaft, the handle member, or the surgical tool to a sterilization step and allowing an indicator to be altered by said exposure to sterilization.

19. The method as recited in claim 13, wherein said indicating step comprises indicating the status on the surgical tool.

20. The method as recited in claim 13, wherein said indicating step comprises indicating a number of

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predetermined procedures to which one of the shaft, the handle, or the surgical tool has been subjected.

21. The method as recited in claim 20, wherein the predetermined procedures comprise one of use during surgery or sterilization.

22. The method as recited in claim 13, wherein said indicating step comprises indicating a number of remaining procedures to which one of the shaft, the handle, or the surgical tool may be subjected during its useful life.

23. The method as recited in claim 22, wherein the predetermined procedures comprise one of use during surgery or sterilization.

24. A minimally-invasive surgical instrument comprising:
a shaft;
a surgical tool secured to said shaft;
a handle secured to said shaft and spaced from said surgical tool;
an actuator associated with said shaft, and operably linked with said surgical tool and operably linkable with said handle; and
an actuator locking member movable along said handle between a first position securing said actuator to said handle and operably linking said handle with said surgical tool and a second position allowing said actuator to move freely of said handle.

25. The surgical instrument as recited in claim 24, wherein said actuator locking member is permanently secured to said handle in either of its first or second positions.

26. The surgical instrument as recited in claim 25,

wherein said actuator locking member comprises a captured screw.

27. The surgical instrument as recited in claim 24, wherein said actuator comprises an actuating rod carried within said shaft and rotatably and axially movable relative thereto, and said actuator locking member is constructed and arranged to permit rotation of said actuating rod within said shaft but to prohibit axial movement between said actuating rod and said handle when said actuator locking member is in said first position.

28. The surgical instrument as recited in claim 24, wherein said handle includes a first bore for receiving an end of said actuator and a second bore contiguous with said first bore for receiving said actuator locking member.

29. The surgical instrument as recited in claim 28, wherein said actuator locking member is permanently secured to said handle in either of its first or second positions.

30. The surgical instrument as recited in claim 29, wherein said actuator locking member comprises a captured screw.

31. The surgical instrument as recited in claim 30, wherein said surgical tool is movable between a first and a second operating position, said handle is movable between a first and a second handle position, and said actuator comprises an actuating rod mounted within said shaft and movable axially relative thereto and is operably linked to said surgical tool and operably linked to said handle and movable between a first and a second actuator position corresponding to said first and second operating positions and said first and second handle positions.

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32. The surgical instrument as recited in claim 24, wherein said surgical tool is movable between a first and a second operating position, said handle is movable between a first and a second handle position, and said actuator comprises an actuating rod mounted within said shaft and movable axially relative thereto and is operably linked to said surgical tool and operably linked to said handle and movable between a first and a second actuator position corresponding to said first and second operating positions and said first and second handle positions.

33. The surgical instrument as recited in claim 24, wherein said shaft is constructed and arranged to pass through a laparoscopic cannula.

34. A minimally-invasive surgical instrument comprising:
a shaft;
a surgical tool secured to said shaft;
a first handle secured to said shaft and separated from said surgical tool;
a second handle pivotally securable to said first handle, between first and second handle positions;
an actuator associated with said shaft and operably linking said second handle with said surgical tool; and
a handle assembly locking member movable between a first handle assembly locking position pivotally securing said second handle to said first handle, and a second handle assembly locking position in which said second handle is not pivotally secured to said first handle and said actuator is released from said second handle.

35. The surgical instrument as recited in claim 34, wherein said second handle includes a slot for receiving an end of said actuator, said slot including a constriction preventing said end of said actuator from escaping said slot when said second handle is pivotally secured to said first

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handle, whereby said actuator can escape said slot when said second handle is not pivotally secured to said first handle.

36. The surgical instrument as recited in claim 34, wherein said handle assembly locking member is permanently secured to one of said first or said second handles in either of said first or second handle assembly locking positions.

37. The surgical instrument as recited in claim 34, wherein said handle assembly locking member comprises a captured screw.

38. The surgical instrument as recited in claim 34, wherein said shaft is constructed and arranged to pass through a laparoscopic cannula.

39. A minimally-invasive surgical instrument comprising:
a shaft having a distal portion residing within a patient during surgery and a proximal portion residing outside of the patient;

a lever secured to said proximal portion of said shaft for manipulation by an operator;

a surgical tool removably secured to said distal portion of said shaft and removably secured to said lever.

40. A surgical tool mountable on a distal end of a shaft of a minimally-invasive surgical instrument, comprising:

a tool member movable between a first and a second position;

a clevis having a portion mounting said tool member and a portion insertable into the distal end of the shaft, said portion insertable into the shaft having means for securing said clevis to the shaft in spaced relation from the distal end of the shaft.

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41. The surgical tool as recited in claim 40, wherein the shaft includes interior threads in spaced relation from the distal end thereof, and said clevis includes exterior threads engagable with the interior threads of the shaft.

42. The surgical tool as recited in claim 40, wherein said portion of said clevis mounting said tool member has a length, and said portion of said clevis insertable into the distal end of the shaft has a length greater than said length of said clevis portion mounting said tool member.

43. A laparoscopic surgical instrument comprising:
a shaft constructed and arranged to pass through a laparoscopic cannula, said shaft having a proximal end and a distal end, said distal end residing within a patient during surgery while said proximal end resides outside of the patient;

a handle assembly comprising a first handle removably secured to said proximal end of said shaft and a second handle pivotally connected to said first handle, said first and second handle members being pivotable relative to each other between first and second handle assembly positions, said shaft being rotatable about its axis relative to said first handle member to which it is secured;

an actuating rod and surgical tool assembly comprising a surgical tool removably secured to said distal end of said shaft and rotatable therewith and movable between a first and a second operating position, and an actuating rod mounted within shaft and movable axially relative thereto between a first and a second actuating position, said actuating rod being permanently secured and operably linked to said surgical tool and operably linked to said second handle to effect movement in said surgical tool between said first and second operating positions when said handle assembly is pivoted between said first and second handle assembly positions, respectively;

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a locking member on said second handle movable between a first position securing said actuating rod to said second handle and a second position in which said actuating rod is not secured to said second handle.

44. A minimally-invasive surgical instrument comprising a shaft having a proximal end and a distal portion, said distal portion residing within a patient during surgery and said proximal end residing outside of the patient, said distal portion securable to a surgical tool movable between a first and a second operating position;

a handle secured to said proximal end of said shaft and movable between a first and a second handle position;

an actuator mounted within said shaft and movable axially relative thereto between a first and a second actuator position, said actuator operably linked to said handle and operably linkable to said surgical tool to effect movement in said tool between said first and second operating positions when said handle is moved between said first and second handle positions, respectively; and

a ratchet piece mounted adjacent said actuator on one of said proximal end of said shaft or said handle, such that when said actuator moves between said first and second actuator positions said ratchet piece is positioned adjacent any of a continuum of locations on said actuator between a first and a second point, said ratchet piece being movable between a first ratchet piece position in which said actuator is freely movable between said first and second actuator positions, and a second ratchet piece position in which said ratchet piece engages said actuator at any of said continuum of locations and prevents said actuator from movement.

45. The surgical instrument as recited in claim 44, wherein said shaft is constructed and arranged to pass through a laparoscopic cannula.

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46. The surgical tool as recited in claim 39, wherein said lever comprises a handle.

47. A method of indicating status, with respect to useful life, of a surgical instrument, the method comprising: providing a surgical instrument; employing the surgical instrument in a procedure; and indicating the status on the surgical instrument.

48. The method as recited in claim 47, wherein the procedure is a surgical procedure.

49. The method as recited in claim 47, wherein the procedure is a sterilization procedure.

50. The method as recited in claim 47, wherein said indicating step comprises making a mark on the surgical instrument.

51. The method as recited in claim 47, wherein said indicating step comprises moving a positionable indicator from a first position to a second position.

52. The method as recited in claim 47, wherein said indicating step comprises altering a mark on the surgical instrument in a way that the mark is distinguishable from an unaltered state.

53. A surgical instrument having a body including an indicator for indicating the status, with respect to useful life, of said instrument.

54. The surgical instrument as recited in claim 53, wherein the body comprises:

a shaft;
a handle secured to said shaft; and

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a surgical tool secured to said shaft and spaced from said handle,

wherein the indicator indicates the status, with respect to useful life, of the shaft, the handle member, or the surgical tool.

55. The surgical instrument as recited in claim 53, wherein the status of said instrument may be determined by viewing said indicator with the naked eye.

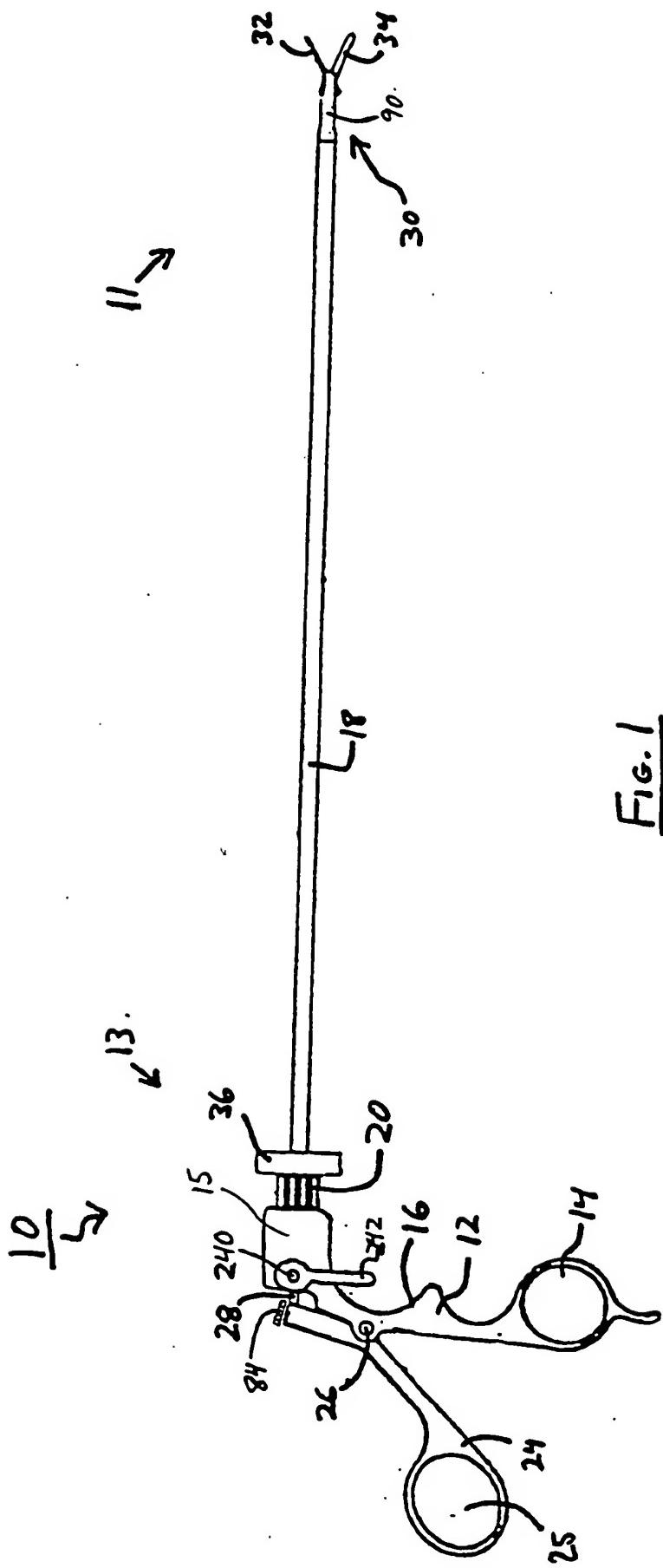
56. The surgical instrument as recited in claim 53, wherein said indicator comprises a plurality of indicia, each of which may be altered by an operator so as to be distinguishable from an unaltered state.

57. The surgical instrument as recited in claim 53, wherein said indicator comprises a material providing a first indication prior to a sterilization step and automatically providing a second indication distinguishable from the first indication subsequent to the sterilization step.

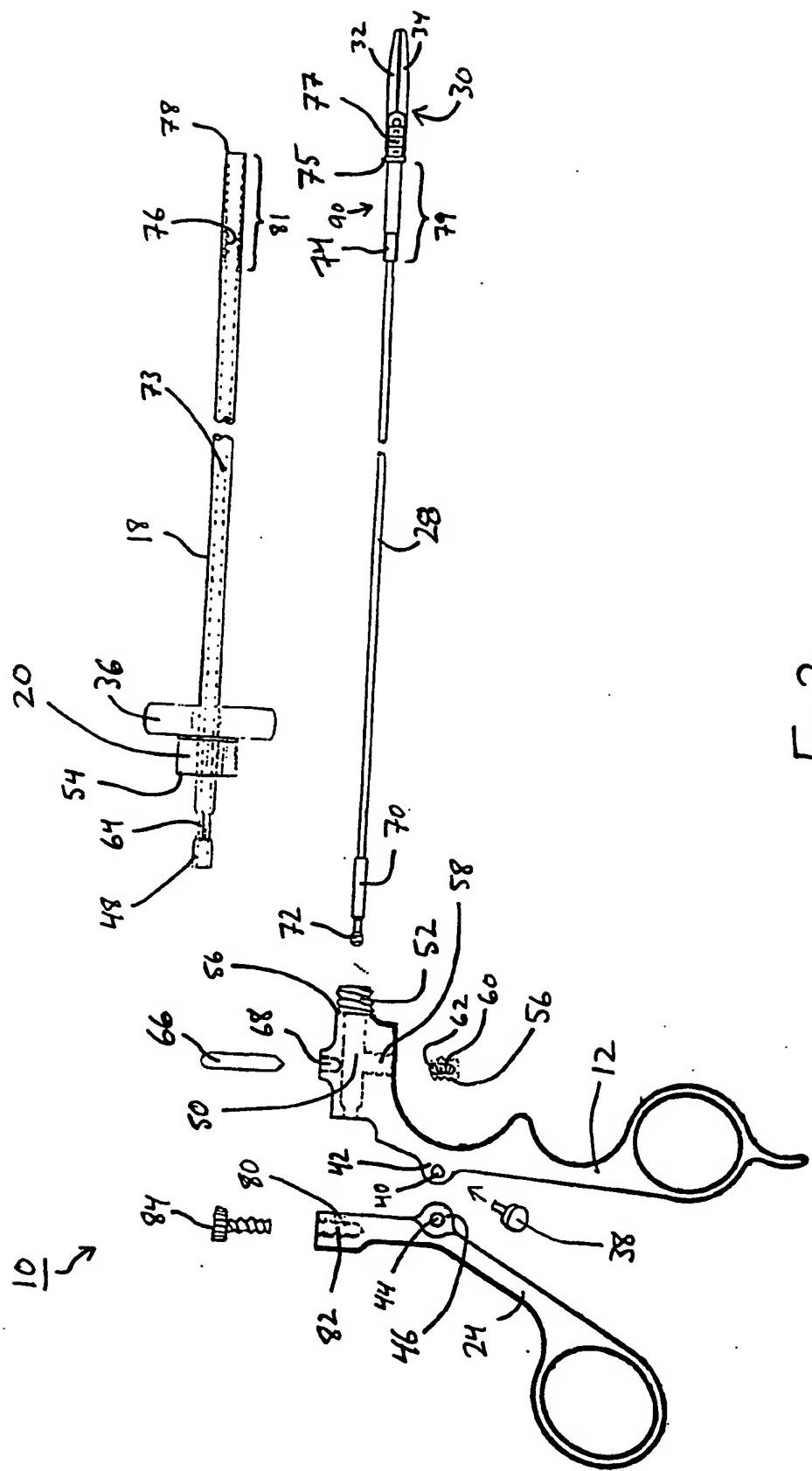
58. The surgical instrument as recited in claim 53, wherein said indicator is positionable in a first position and a second position distinguishable from the first position.

59. The surgical instrument as recited in claim 53, wherein said indicator comprises a mark made by an operator of the instrument.

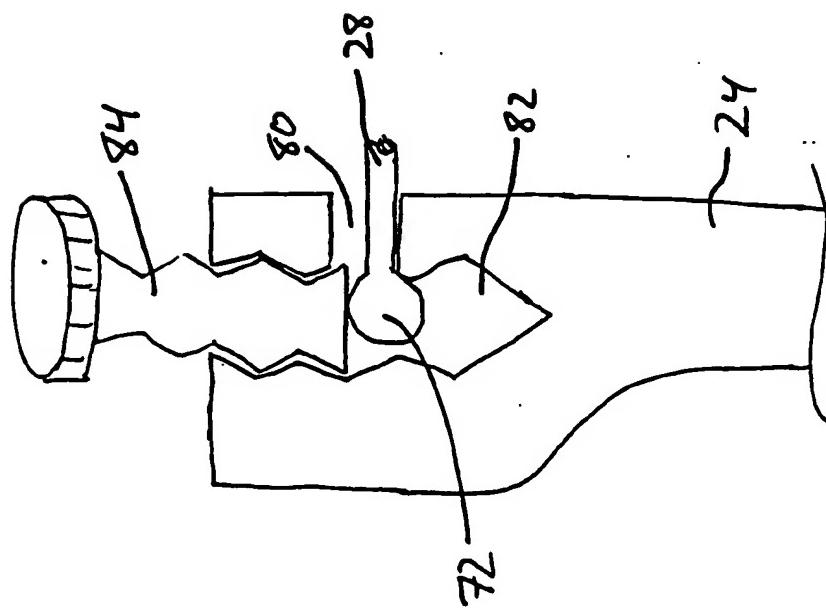
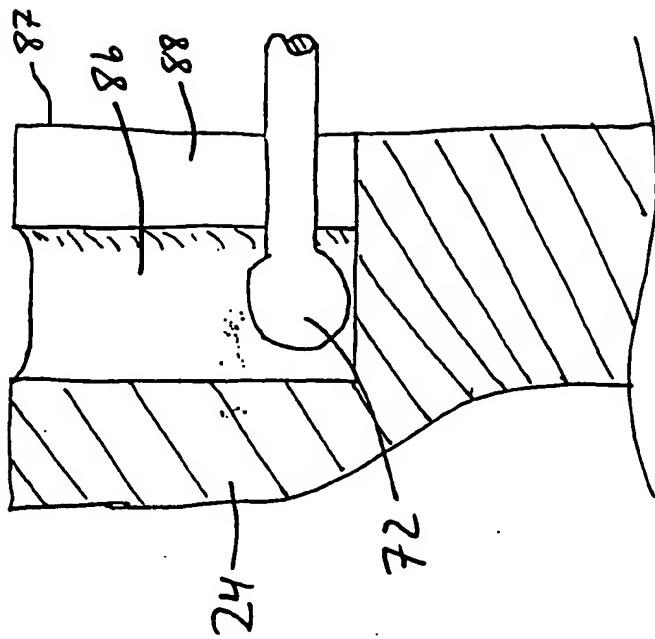
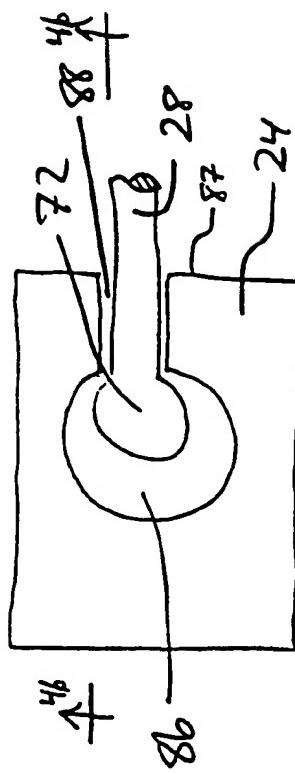
60. The surgical instrument as recited in claim 1, wherein said shaft is constructed and arranged to pass through a laparoscopic cannula.



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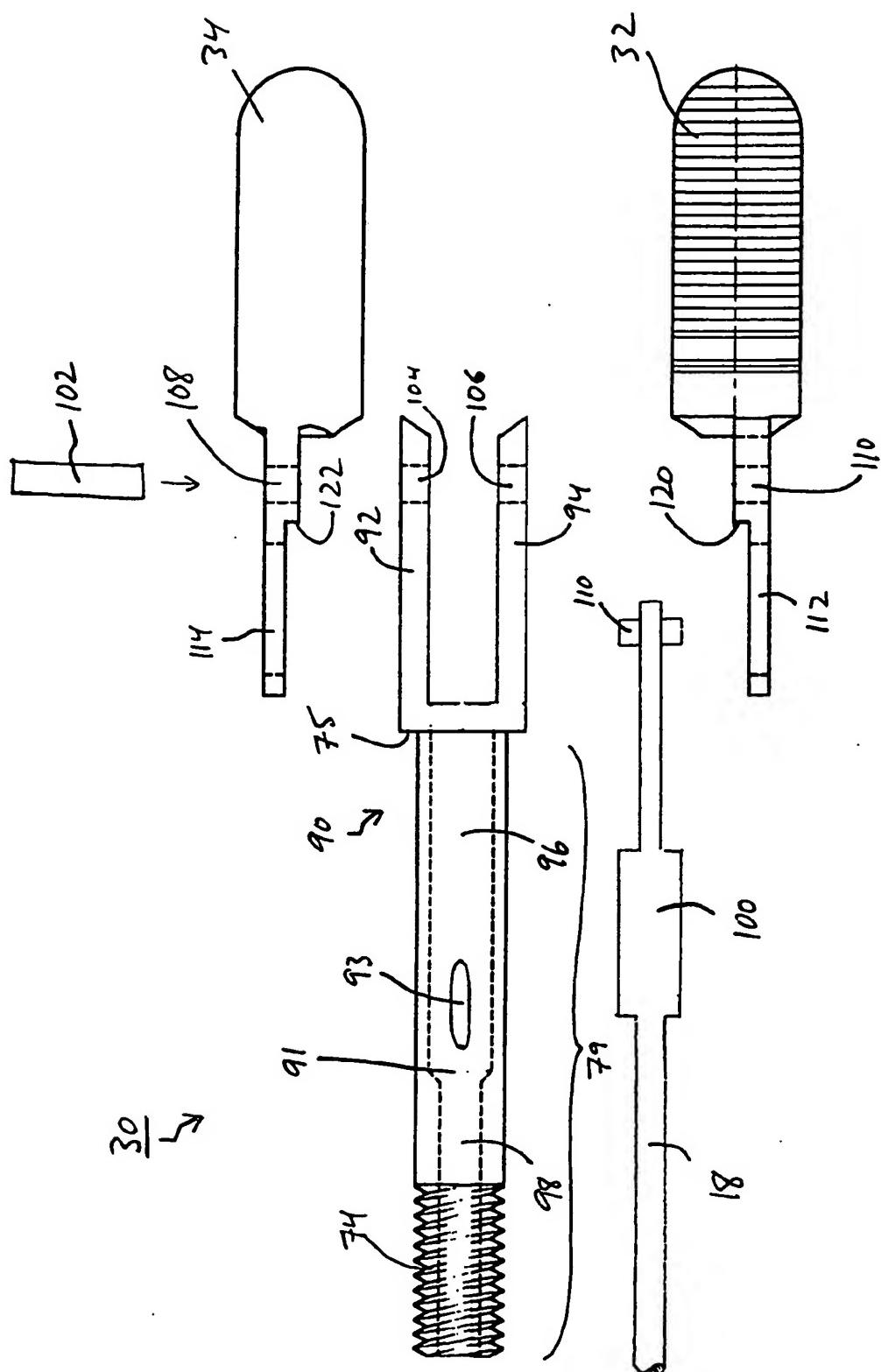
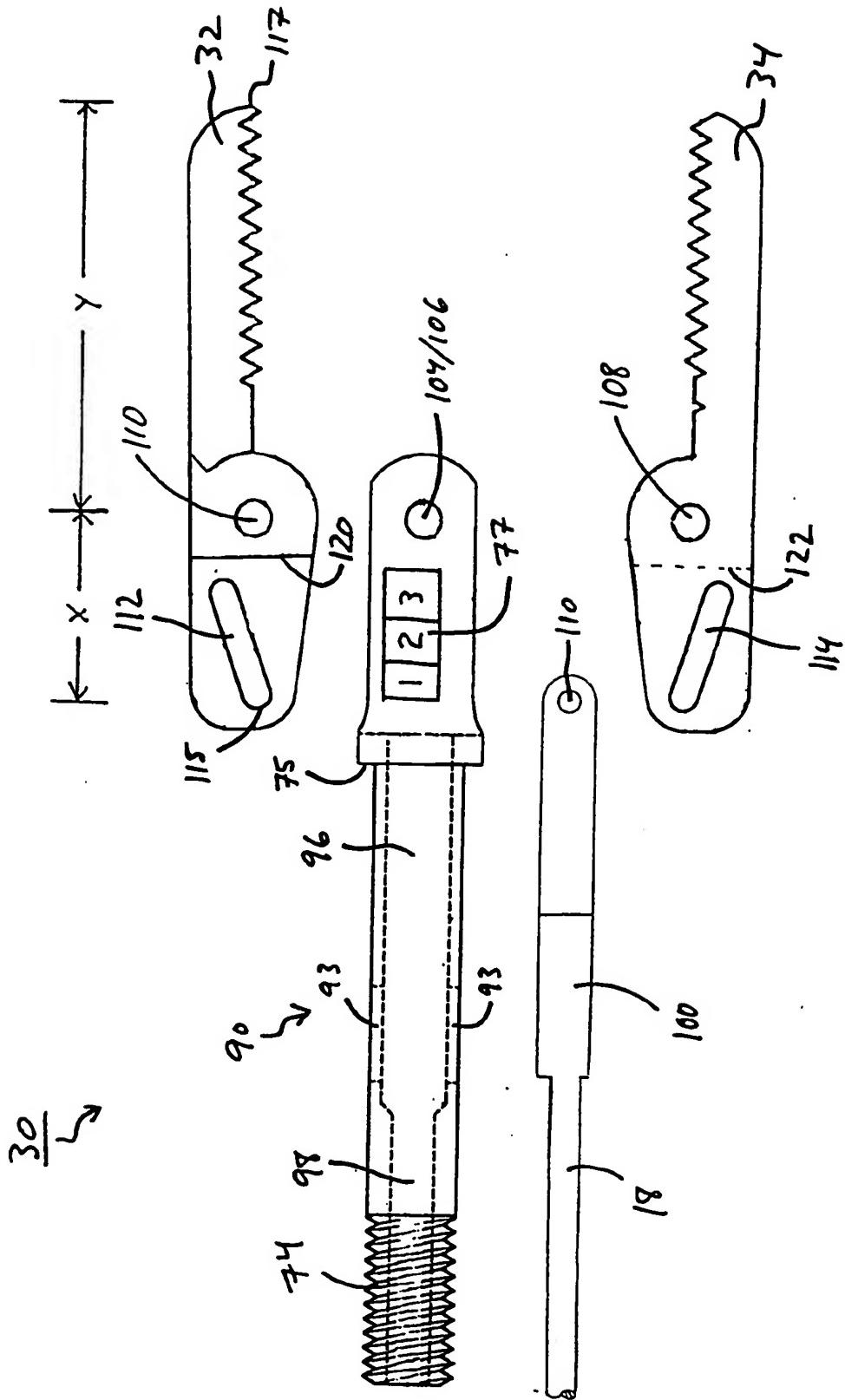
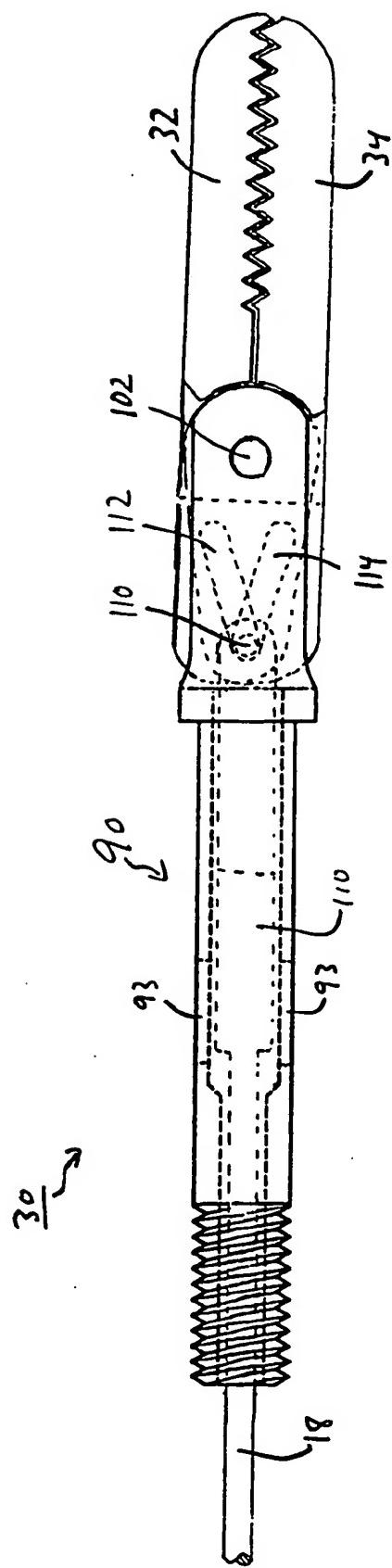
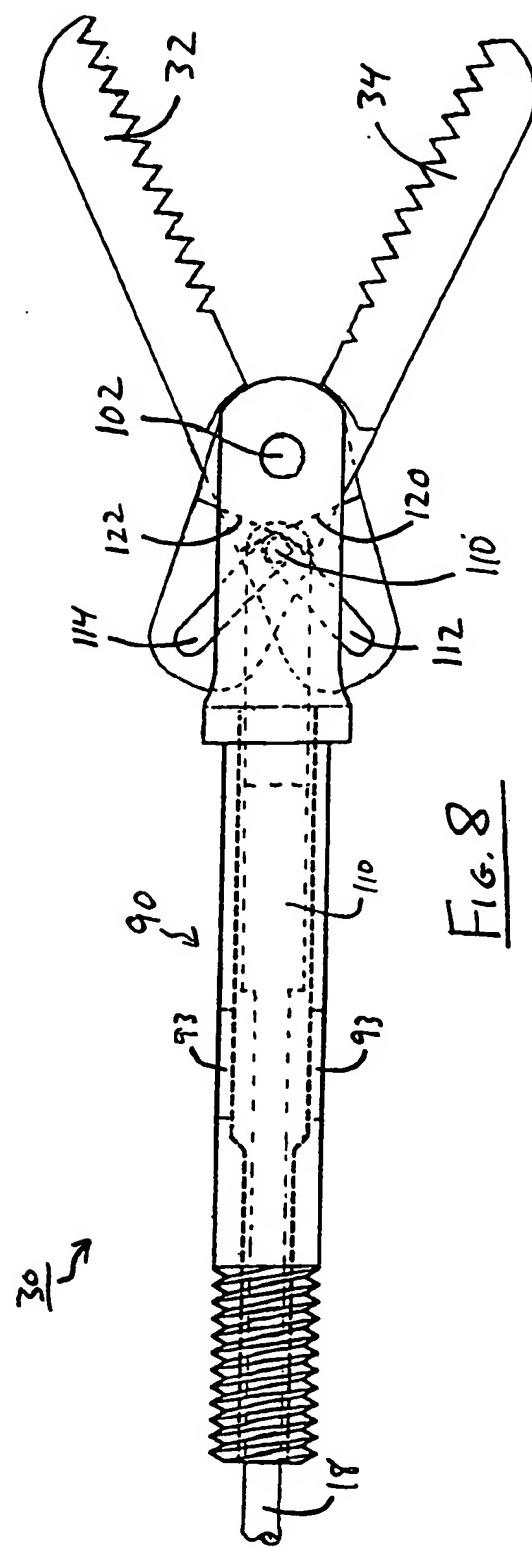


Fig. 5

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Fig. 6

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Fig. 7Fig. 8

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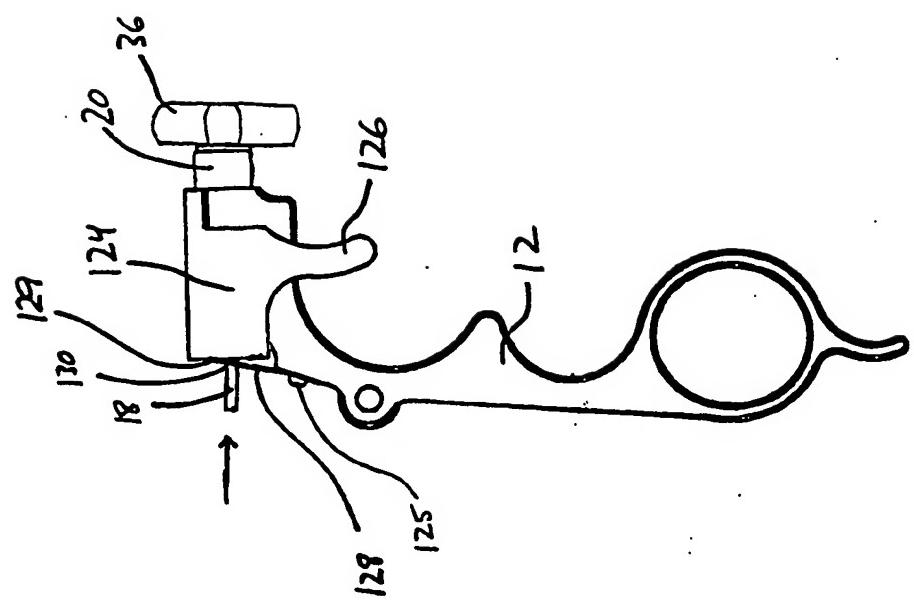


Fig. 9

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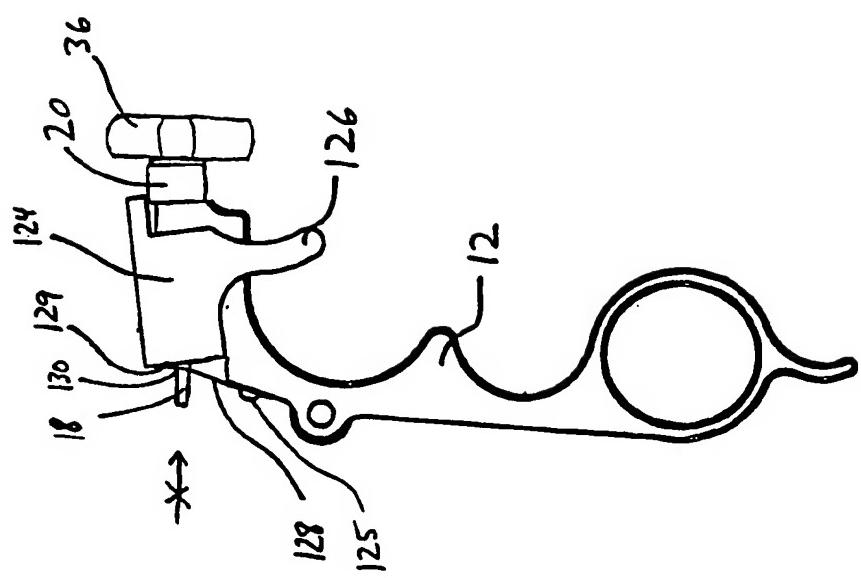


FIG. 10

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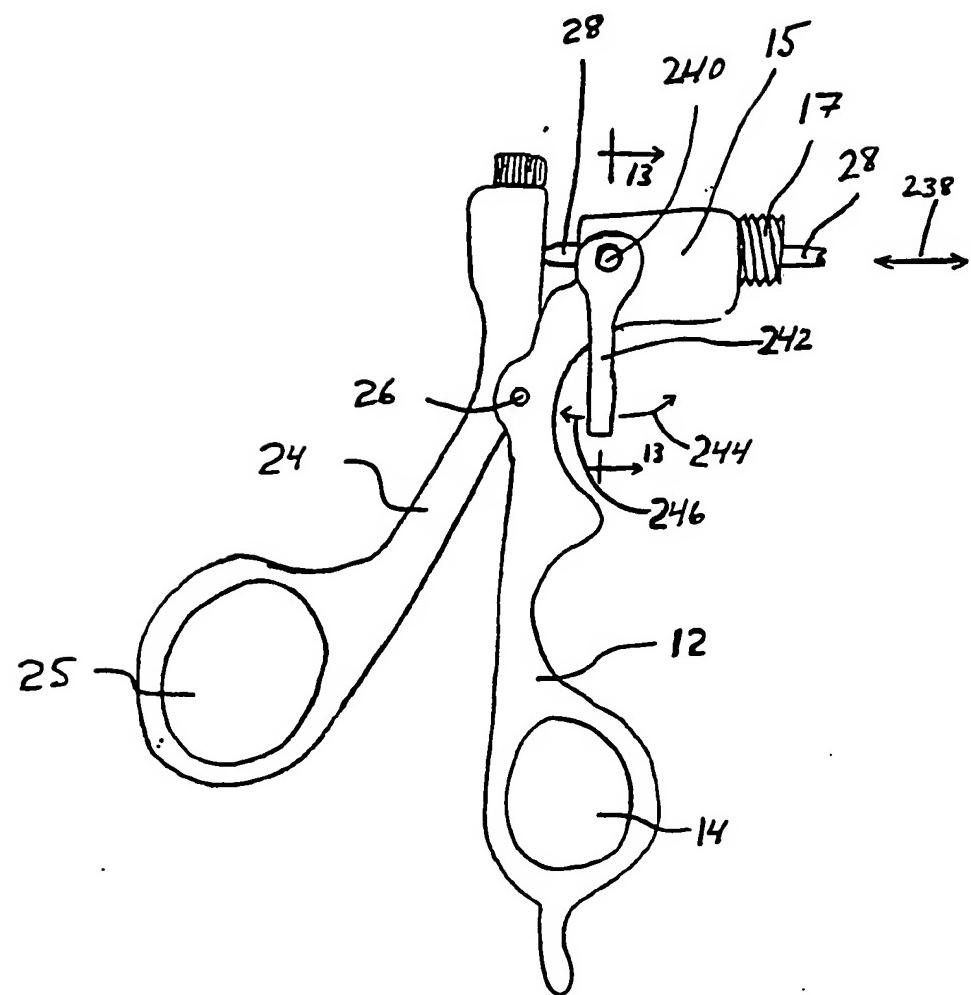


Fig.-11

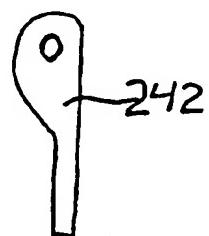


Fig.-12

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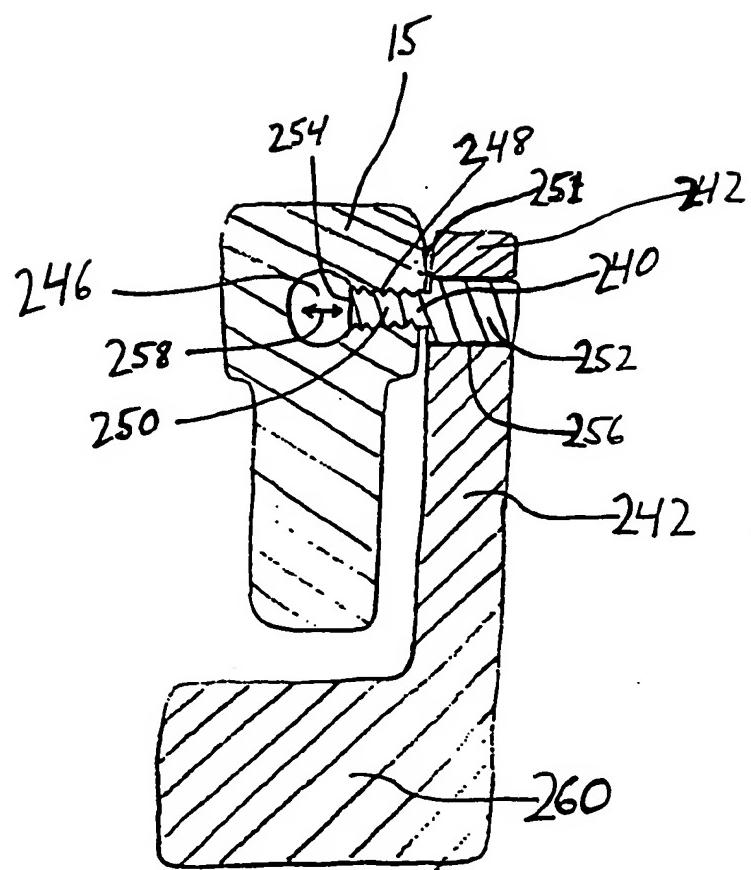


Fig.13

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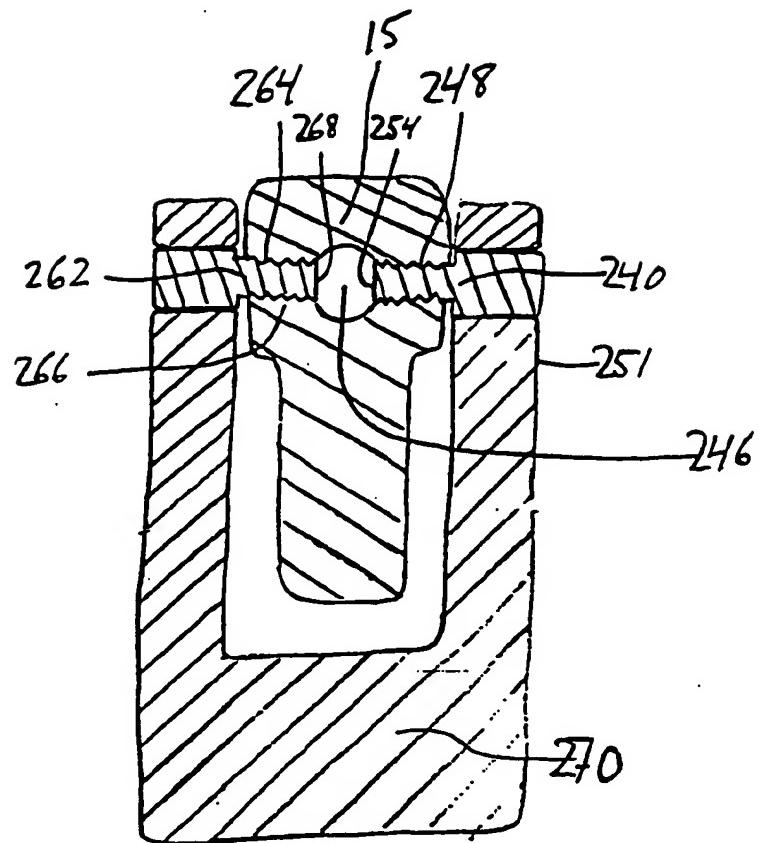


Fig 14

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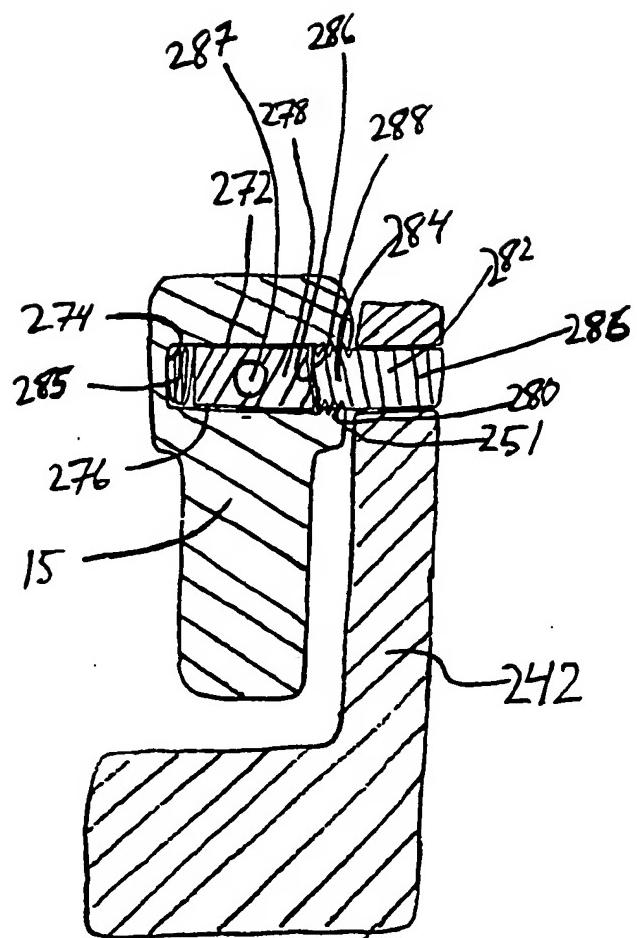


Fig. 15

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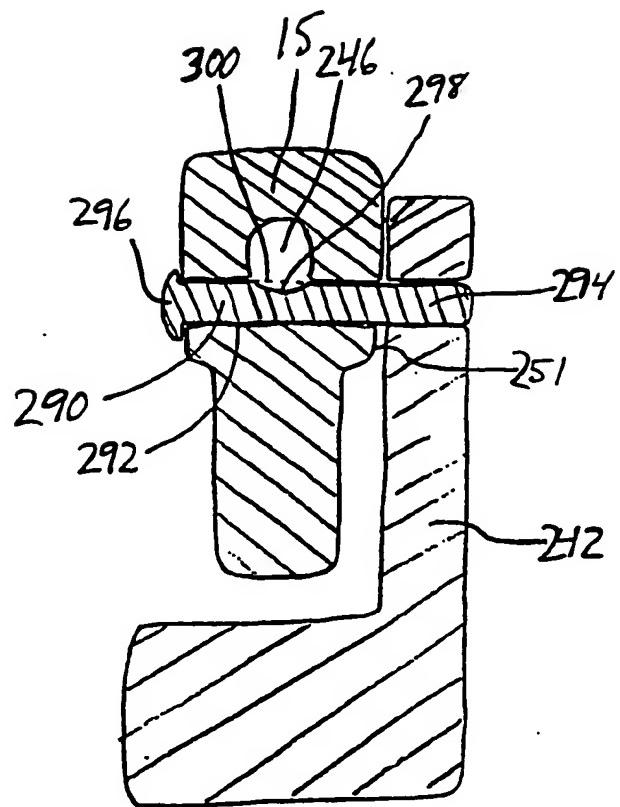


FIG. 16

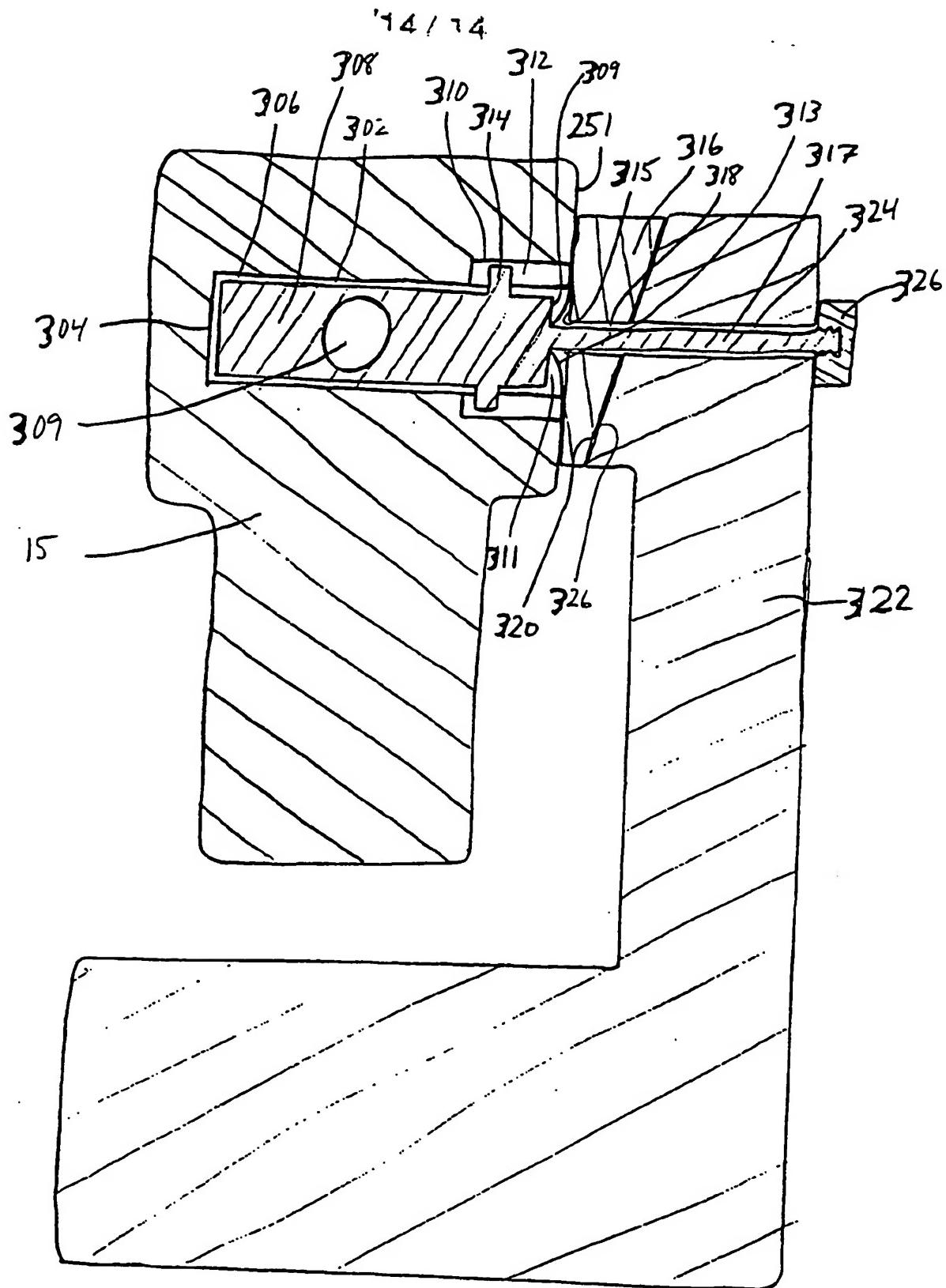


FIG. 17



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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(74) Agent: HONEYMAN, Jason, M.; Wolf, Greenfield & Sacks, P.C., 600 Atlantic Avenue, Boston, MA 02210 (US).			
(54) Title: MINIMALLY-INVASIVE SURGICAL INSTRUMENT AND MODIFIED RATCHET			
(57) Abstract <p>A minimally-invasive surgical instrument is provided including front and rear handles mounted pivotally relative to each other. A shaft is mounted to the front handle and an actuating rod connected to the rear handle passes through the shaft and is moveable longitudinally relative thereto, the actuating rod having a proximal end coupled to the rear handle and a distal end coupled to a jaw assembly. The jaw assembly may be securely fastened at the distal end of the shaft. Cleaning holes may be provided at strategic locations in the instrument for cleaning capability and individual components of the instrument are interchangeable with other components to provide flexibility in terms of shaft length, jaw assembly function, and the like. The instrument is specifically designed so that any interchange of instrument components may be effected only by releasing securing mechanisms at portions of the instrument that remain outside of a patient during surgery. The instrument may be provided by captured fasteners so that loss and/or contamination of fasteners is avoided. The instrument can include a modified ratchet mechanism including a trigger movable by a surgeon and an impinging member mounted adjacent the actuating rod and secured to the trigger and movable from a position allowing the actuating rod to move longitudinally relative to the shaft, and a position securing the rod against such movement.</p>			

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INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 94/13004

A. CLASSIFICATION OF SUBJECT MATTER
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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61B A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP,A,0 565 049 (U.S.S.C.) 13 October 1993 see the whole document	1-3,5, 24-33,60
Y	---	35,36,38
A	---	44
Y	DE,A,43 11 770 (OLYMPUS OPTICAL CO., LTD.) 28 October 1993 see abstract; figures ---	35,36,38
X	EP,A,0 555 105 (SYMBIOSIS CORPORATION) 11 August 1993 see the whole document ---	24-38
X,P	DE,U,94 01 556 (KARL LEIBINGER MEDIZINTECHNIK GMBH & CO. KG) 17 March 1994 see the whole document -----	1-5, 24-38, 44,45,60



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

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Date of the actual completion of the international search

Date of mailing of the international search report

10 March 1995

01.06.95

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
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Authorized officer

GIMENEZ BURGOS, R

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US 94/ 13004

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos.: because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos.: because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos.: because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Claims 1-5, 24-38, 44, 45, and 60 relate to a laparoscopic surgical tool comprising: shaft; surgical tool; tool manipulator actuator and impinging member.
The impinging member blocks or releases the actuator in any position.

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.

2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

1-5, 24-38, 44, 45 and 60

Remark on Protest

 The additional search fees were accompanied by the applicant's protest. No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte: Int'l Application No:

PCT/US 94/13004

Patent document cited in search report	Publication date	Patent family member(s)		Publication date
EP-A-0565049	13-10-93	US-A-	5314424	24-05-94
DE-A-4311770	28-10-93	JP-A-	6007366	18-01-94
		JP-A-	5285149	02-11-93
		US-A-	5370659	06-12-94
EP-A-0555105	11-08-93	AU-B-	655530	22-12-94
		AU-B-	3656993	03-09-93
		CA-A-	2088868	07-08-93
		JP-A-	6014876	25-01-94
		WO-A-	9315663	19-08-93
		US-A-	5293878	15-03-94
DE-U-9401556	17-03-94	NONE		